Exhibit C

APPENDIX

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EXHIBIT 1

Declaration of Graham T. Chelius, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF GRAHAM T. CHELIUS, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Graham T. Chelius, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge and if called to testify I could and would do so competently as follows.

2. I am a plaintiff in the above-captioned litigation, which challenges the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex. I provide this declaration in support of that litigation. I do so in my individual capacity, and not on behalf of any entity with which I am associated or where I practice, including my employer, Hawaii Health Systems Corporation.

3. I am a board-certified Family Medicine physician based on the island of Kaua'i in Hawai'i. I practice medicine at Kauai Veterans Memorial Hospital ("Kauai Veterans") and its associated clinics, West Kauai Clinics. Kauai Veterans is located on the western side of the island in the town of Waimea, Kaua'i. Kauai Veterans currently employs about 275 people.

4. I am currently the Chief of Staff at Kauai Veterans, a position I have held since February 2018. Immediately before that, and after serving for several years as a board member, I served as the Chief Medical Officer for the Hawaii Health Systems Corporation's Kaua'i Region (which, in addition to Kauai Veterans, included Samuel Mahelona Memorial Hospital, on the eastern side of the

island in Kapa‘a, Kaua‘i), but resigned from that position in December 2017 in favor of this new opportunity as Chief of Staff. In my role as Chief Medical Officer, I was primarily responsible for managing the relationship between Hawaii Health Systems Corporation and the physicians who serve the Kaua‘i region, including participating in contract negotiations, overseeing physician staffing assignments, and responding to any complaints brought against physicians by both patients and staff. As Chief of Staff, I have very similar responsibilities, but rather than acting as a representative of the administration I am an elected representative of the physicians who form the medical staff. Both my current and former positions require that I be involved in resolving most conflicts that arise among the small clinical team at Kauai Veterans.

5. I received my medical degree from the University of Wisconsin in 2001, and completed my residency in Family Medicine at North Colorado Medical Center. Since January 2009, I have been practicing medicine in Hawai‘i at Kauai Veterans.

6. In my current role as Chief of Staff, I continue to treat patients. Within my specialty of Family Medicine, I focus in particular on women’s health, including obstetrics, and on chemical dependency treatment.

7. During the twelve years that I have been practicing medicine in Hawai‘i, I would estimate that I have cared for more than 2,750 pregnant patients

and delivered over 1,100 babies on the island of Kaua‘i. While many of my patients have much-wanted pregnancies, a substantial percentage choose to end their pregnancies, and come to me seeking abortion care. Most of these patients are medically eligible for the FDA-approved medication abortion regimen: Mifeprex followed by the drug misoprostol.

8. However, I am unable to prescribe Mifeprex to patients who need this medication because, as detailed below, complying with the requirements in the REMS that I procure, stock, and dispense Mifeprex at my health care facility—rather than issuing a prescription, from the privacy of my office, for my patient to fill at a pharmacy—would damage my professional standing locally, disrupt the workplace dynamics I am responsible for maintaining, interfere with my ability to continue to serve the many patients I now serve, and jeopardize my patients' confidentiality. The Mifeprex REMS deters clinicians and harms patients by imposing unique, unnecessary, and onerous requirements on their care. Put plainly, the REMS impedes my and other clinicians' ability to safely and appropriately care for our abortion and miscarriage patients as we would patients seeking any other service.

9. The distribution restriction substantially interferes with my ability to practice medicine in accordance with my professional judgment. Because of the Mifeprex REMS, I am unable to provide medication abortions to my patients, even

in situations when my best medical judgment would strongly counsel in favor of providing this care.

10. There is only a narrow window in which a patient can take the Mifeprex-misoprostol regimen for early pregnancy termination: this method has been approved by FDA only for the first ten weeks of pregnancy, and that is the period during which clinicians generally prescribe it. But patients cannot know they are pregnant until four weeks, and many patients do not realize they are pregnant until their sixth to eighth week. By the time a patient sees me, they typically have only a few weeks—indeed, often only a few days—in which to take the medications. If they cannot access Mifeprex within the window of availability, the only option is a surgical abortion. Nevertheless, because of the REMS, I am unable to provide medication abortion care in these time-sensitive situations.

11. There are no abortion providers on Kaua‘i, a federally designated "medically underserved area." The closest provider of abortion services is on O‘ahu, which can be reached only by airplane. I have seen the anxiety and confusion in my patients' eyes when I tell them that they have to fly to O‘ahu to obtain an abortion. I have heard them describe their frustration, anger, and heartbreak. For some patients—many of whom are already experiencing significant anxiety as a result of the unwanted pregnancy, and some of whom are also struggling with the challenges and trauma of poverty, drug addiction,

joblessness, and/or domestic violence—this news is simply devastating.

12. Traveling to O‘ahu for a surgical abortion costs my patients money and time, and causes them stress. Many are forced to make significant personal and financial sacrifices in order to get the health care they need. They must find the money to pay, or if possible make arrangements for insurance to pay, for the costs of transportation to and from the airports on both islands, and for the flights themselves. They must arrange to take time off from work or school, and arrange for child care if they have children, which most do. If a loved one is accompanying them to O‘ahu for support, that person must bear these costs as well. This travel and related logistics also impose significant psychological and emotional strain on many of my patients, and in my experience can be especially hard on young women, women struggling with substance abuse, women for whom English is not their first language, and women who are homeless.

13. Raising the money and making arrangements to travel is often time-consuming. Given the circumstances of my patients’ lives, it is not uncommon for it to take several weeks, a month, or longer. Indeed, even for those of my patients fortunate enough to have insurance coverage for the abortion procedure and the travel to obtain it (though, of course, still not for child care, missed work, or food away from home), it typically takes one to two weeks just for the paperwork to be approved. As previously noted, delays often mean that patients are no longer

eligible for medication abortion at all, and instead must have a surgical procedure. Moreover, while abortion is very safe, the risks increase as pregnancy advances. And, on top of that, patients whose abortions are delayed also face health risks associated with continuing a pregnancy for additional days, weeks, or months. For such patients, delaying their abortion means they are sicker, longer.

14. I recall one patient whose experience powerfully illustrates many of the harms caused and burdens created by the REMS. She is a woman whom I had been treating for substance use disorder and who had previously seen us for obstetrical care for her first child. She came to my office seeking an abortion prior to 10 weeks of pregnancy. After evaluating her, I concurred that a medication abortion was an appropriate treatment, that she could utilize the Mifeprex-misoprostol regimen, and that she should do so without delay. I wanted to—and would have—provided her with the medication abortion she desired if I could have written a prescription for Mifeprex for her to fill at a pharmacy. But, because of the REMS, I could not provide that care to my patient. Instead, she was forced to travel to O‘ahu.

15. Because of the complications in this woman’s life, by the time she was finally able to make the journey to O‘ahu, more than six weeks had passed. At that point, she had to have a two-day dilation and evacuation (“D&E”) abortion instead of the medication abortion she had wanted. Not only is D&E a significantly

more complex and invasive procedure, but it also required her to bear the costs of staying on O‘ahu—in a hotel, away from her home and her family—overnight. This was utterly unaffordable for her. Indeed, I understand that she called her sister on the day of her first appointment to tell her that she was on O‘ahu for an abortion and had only $20 in her pocket. Her sister jumped on the plane to help my patient find lodging and provide her with emotional support during the procedure—which of course meant that my patient’s sister also had to bear the costs of a round-trip flight, hotel, and food during her stay. Fortunately, her sister managed to drop everything and come to her aid, but otherwise I don’t know how she would have managed to get to and from her appointments or where she would have stayed overnight.

16. I still feel frustrated and upset that my patient and her family had to bear the emotional trauma, financial burdens, and medical risks of this experience. And she is far from the only patient I have had who was eligible for medication abortion at the time I saw her, but ultimately had to not only fly to O‘ahu to get the care they needed, but by the time they did so were too late for a medication abortion and had to have a procedure instead. Again, none of this would be necessary if I could have simply written this patient, and other patients like her, a prescription for Mifeprex when she was in my office early in her pregnancy.

17. While that patient *was* ultimately able to get an abortion—not all of my patients are. In some cases, the travel burdens created by the Mifeprex REMS are simply untenable, and my patients end up carrying pregnancies to term and having children against their will. For instance, one patient who struggles with chemical dependency never was able to get to O‘ahu, despite her expressed desire for an abortion and despite extensive assistance with the travel arrangements. As a result, she was forced to carry the pregnancy to term (and her child was exposed to drugs throughout the entire pregnancy). I have continued to care for such patients through the course of their pregnancies and beyond, and have seen firsthand the emotional, physical, and financial burdens that an unwanted pregnancy can cause.

18. Sadly, the situation is even worse for women who live on Ni‘ihau, which is a sparsely populated island just west of Kaua‘i. There are no paved roads, and no cell coverage—let alone health care—on Ni‘ihau. Because of the lack of access to reproductive health care on-island, women on Ni‘ihau have to schedule transportation by boat to Kaua‘i just to see a doctor. My hospital delivers virtually all the babies for pregnant women on Ni‘ihau. If a woman on Ni‘ihau wants to terminate her pregnancy, the obstacles are even greater for her than for a woman on Kaua‘i. But if the REMS did not exist, she could simply go to Kaua‘i to obtain Mifeprex the same day, instead of going to Kaua‘i only to then get referred to an O‘ahu-based abortion provider and facing all the associated obstacles. I mention

Ni‘ihau just to show how burdens can aggregate and compound into an entirely insurmountable barrier to accessing safe abortion care.

19. I became a doctor to make my patients’ lives easier, less painful, and more fulfilling. But, because of the REMS, I must watch them suffer medical, emotional, and financial burdens when I cannot provide them with the abortion care that they desire. In addition, as a physician, I am concerned about continuity of care—yet the restrictions imposed by the Mifeprex REMS mean that I must needlessly hand off my patients to someone else for care, breaking that continuity for absolutely no medical reason. While I am confident that the providers to whom I refer my patients in O‘ahu provide high-quality care, it pains me to have to turn my patients away and send them off island to get care they need and that I am perfectly competent to provide. The Mifeprex REMS thus prevents me from providing uninterrupted, comprehensive primary health care to my patients, as I strive to do whenever possible. It violates my fundamental beliefs as a health care provider to have to deny a patient’s request for time-sensitive, medically indicated care only because of medically unjustified restrictions like the Mifeprex REMS.

20. For the past several years, some of my patients have been able to avoid most of these burdens by participating in the Telemedicine Abortion Study (“TelAbortion”), which is run through the University of Hawai‘i. This study—which I understand operates as a temporary waiver of the REMS—allows certain

qualifying patients to receive Mifeprex by overnight mail from the study's principal investigators on O'ahu without having to fly to that island for care. Recognizing how difficult the journey to O'ahu is for many of my patients, wherever possible, I have assisted them in participating in the study. I believe this model of care delivery—mailing Mifeprex following a telemedicine visit—is safe and effective and a valuable option for my patients.

21. But the TelAbortion study's process carries its own burdens and complexities, and therefore excludes the most vulnerable, highest-risk patients. The cost of participation in TelAbortion presents the first hurdle. While the State of Hawai'i generally covers the cost of abortion services through its Medicaid program, it does not cover the cost of Mifeprex obtained through the TelAbortion study. Thus, Medicaid enrollees must pay out-of-pocket for Mifeprex provided through the study. This effectively excludes or deters many lower-income patients from participating.

22. The logistics are another hurdle. In most cases, the study protocols require that a participating patient first have a blood test and ultrasound performed, and then mail, fax, or email the results to a physician at the University of Hawai'i. Then, that physician must connect with the patient by secure videoconference at a set appointment time. Some of my patients—including some who are homeless, poor, or live in extremely remote parts of Kaua'i—do not have reliable internet or

cell phone service, access to technology with secure videoconferencing capability, or the ability to use this technology in a private space where they can speak confidentially. In such cases, I often have to step in to help them. On several occasions, I have stayed late at my office to let a patient use my computer to participate in the study, but this is not always possible: my patients' schedule, my schedule, and the schedule of the physicians on O'ahu do not always align, and certainly do not always align before the patient's window for a medication abortion closes. Helping my patients participate in the TelAbortion study has taken, and continues to take, many hours of my time—and even so, some of my patients still cannot successfully use it.

23. A third hurdle is that participating patients must have a physical address to which a package can be securely and confidentially mailed. But my patients who are homeless do not have such a safe address. So the study also cannot provide relief to such patients.

24. For all patients, even if they can gather the resources to participate in TelAbortion, the processes and requirements of participating in a research study delay care. I have on numerous occasions seen patients who were still within the window for a medication abortion, but did not have enough time to access it through the study.

25. Critically, I understand that the TelAbortion study is only temporary. When it ends, it will no longer exist as an option for me and my patients.

26. The harms and burdens I have described that both my patients and I are experiencing flow directly from my inability to issue a prescription for Mifeprex to be filled at a pharmacy or by mail order as I can do with countless other equally or less safe drugs. Most of these harms and burdens would be entirely eliminated, or substantially reduced, if the REMS were eliminated.

27. In addition, the REMS imposes a broader set of harms by deterring and blocking qualified clinicians from becoming medication abortion providers through its unique and unnecessary barriers. First, in order to comply with the requirement in the REMS that I procure, stock, and dispense Mifeprex at my medical facility, I would have to risk serious damage to my professional standing in my workplace and to my respected role in the local community. Abortion is an issue about which people hold very strong views, and some of my colleagues and staff members strongly oppose it. In my tight-knit workplace, attempting to establish a policy for procuring, stocking, and dispensing Mifeprex at our facility would create internal conflict, undermining the team cohesion that I am responsible for developing and maintaining as Chief of Staff. It would also jeopardize my ability to continue in that elected position, threaten initiatives I am undertaking to improve care within our hospital system, and reduce the time I have

to treat patients. I cannot afford these personal and professional risks.

28. To be clear, many of my colleagues and staff already know that I provide abortion referrals. I know that some staff oppose even this; some have directly expressed such views to me. But if I were to comply with the Mifeprex REMS, I would be doing more than just supporting access to abortion in my *individual* professional capacity—I would also have to involve, and win the approval of, multiple colleagues and staff members in the process of procuring, stocking, dispensing, and billing for Mifeprex within our health care facility. Asking or demanding that my colleagues who have deeply held views against abortion participate or assist in providing abortions would cause significant conflict among my staff—conflict that, as Chief of Staff, I would also be required to manage, if possible. The negative consequences for my professional standing and for carefully nurtured workplace dynamics, which benefit all of our patients, deter me from attempting to comply with the Mifeprex REMS.

29. Relatedly, I also have had serious personal safety concerns about the requirement in the REMS that I register with the drug manufacturer and drug distribution company as an abortion provider. I understand that they must keep confidential the list of clinicians registered to prescribe Mifeprex. But particularly in light of the many recent health care hacking incidents, I have been concerned about being inadvertently or maliciously exposed as an abortion provider, and the

resulting likelihood of public backlash to me and my family.

30. Of course, my name is now public in the context of this litigation, and my experience since filing this lawsuit has validated my earlier concerns. Since the lawsuit was filed, I have received numerous phone calls and letters from strangers relating to this litigation. Many of those communications were positive and supportive. But a few were negative and concerning. Based on security consultations, I now carefully examine envelopes for toxic material, and have tried to remember to only open packages that I have been expecting. We also installed a security system at our house. In a country where abortion clinic shootings are commonplace and abortion providers have been assassinated, I have feared risking my and my family's safety by following through with what the Mifeprex REMS requires.

31. I ultimately made the difficult choice to publicize my desire to provide abortion care through this lawsuit, because I believe this case has the potential to expand access to medication abortion for patients all across the country. My family and I felt that this goal was worth the risk to our safety and privacy. But we did not make that choice lightly, and I expect that I am not the only physician who has found the REMS requirement that I add my name to a list of all medication abortion providers in the country a serious deterrent to providing this care.

32. I am also concerned that compliance with the Mifeprex REMS would jeopardize my patients' privacy. By requiring that my facility be responsible for the purchasing, stocking, dispensing, and billing of Mifeprex—discrete responsibilities held by discrete members of our staff—the REMS injects many more people into the abortion care process. This raises real confidentiality concerns in the small-town community in which I practice. Everybody knows you and you know everybody in Waimea, a town of fewer than 2,000 people on an island of just over 65,000. In fact, it is not uncommon for members of my staff to bump into my patients at the grocery store, gym, or on the street. For myself, going to either of the two grocery stores in Waimea is a social event due to the fact that I will certainly know someone either working or shopping at the store.

33. Additionally, many members of the community have a family member, friend, or neighbor employed at Kauai Veterans, and, as a result, members of our community are sometimes nervous about seeking intimate medical care from us out of fear for their confidentiality. Certain elements of a person's medical history (history of abortion, sexually transmitted diseases such as HIV or gonorrhea, a history of rape, struggles with substance use disorder) are closely guarded by patients due to real or perceived stigma from those in the general population and medical providers.

34. For instance, I have a patient who, while pregnant, asked that a specific doctor not be involved in her care because she was afraid that the provider might divulge her medical history to family members of the doctor whom the patient also knew. Fortunately, I was able to sufficiently reassure this patient that I trust this physician to respect her confidentiality, which resulted in this patient continuing to receive care from us. But there is no doubt that, in our community, patients struggle with the decision of whether to get adequate medical care due to concerns about their confidentiality. And, indeed, it would be entirely reasonable for a patient to fear for the privacy of her abortion decision if she happens to know, for instance, some of the numerous people who may be involved with the billing, ordering, recording, and physical dispensing of medication at our facility (which, again, is a perfectly plausible scenario in our small town).

35. By contrast, if the Mifeprex REMS did not exist, I would be able to write a prescription for Mifeprex for my patient without needing to let anyone else know about the prescription except, at most, the patient's nurse, a medical records clerk, and the patient's trusted pharmacist (or a pharmacy on the other side of the island, or a mail-order pharmacy, if that is the patient's preference). The risk to my patients' confidentiality is thus substantially higher under the Mifeprex REMS.

36. The Mifeprex REMS also presents significant logistical hurdles. In order to stock and dispense Mifeprex onsite, I would need to first get a policy created for storing and dispensing the drug in the clinic, and then secure approval from the Pharmacy and Therapeutics committee at Kauai Veterans. I would also need to complete and submit all of the paperwork associated with becoming a certified prescriber under the Mifeprex REMS and setting up an account with the drug distribution company—a process that would take even more time and effort because the purchasing agreement would need to go through our contracting office, which has to follow burdensome state contracting guidelines and rules.

37. Of course, I am not now a certified prescriber (though I could easily satisfy the stated criteria for prescribing clinicians), because the certification requires me to provide a billing address and a shipping address where the Mifeprex can be sent to and then dispensed from—which, for the reasons I have stated, I am unable to do. And regardless of any certification requirement, I now provide and will always provide only medical care within the scope of practice for which I'm qualified. That is a well-recognized, basic standard of the medical profession.

38. As I have already noted, this approval process would be extremely challenging in the tense political climate surrounding abortion at my hospital, and it would almost certainly be subject to interference by colleagues and others who vehemently oppose abortion and therefore would object to a decision to stock

Mifeprex in our hospital system. As Chief of Staff tasked with maintaining good working relationships in my hospital, I find these risks unacceptable. They would not only interfere with my supervisory role, and the long-term positive changes for overall patient care that I am attempting to accomplish in that role, but also take valuable time away from my own practice.

39. In addition, I understand that the Mifeprex REMS would also require me to provide my patients with, and discuss and sign, a "Patient Agreement Form" describing the proper usage of, and risks associated with, Mifeprex as of March 2016. This special form requirement is unnecessary and singles out abortion in a manner that other medications, even much less safe medications, are not.

40. Informed consent counseling is a bedrock of medical care, taught as a core skill in medical school and reinforced by the American Medical Association's Code of Medical Ethics. I do not need any special requirement or form to ensure that I provide every patient with informed consent counseling, including discussion of proper usage and risks and what to do in the event that they need follow-up or emergency care. In fact, much less safe medications that I use in my chemical dependency practice, such as Sublocade®, which are controlled substances and are very high risk for patients, do not require any such "patient agreement form." Nor do the many other medications that I prescribe, that patients fill at a pharmacy, and that they take at home.

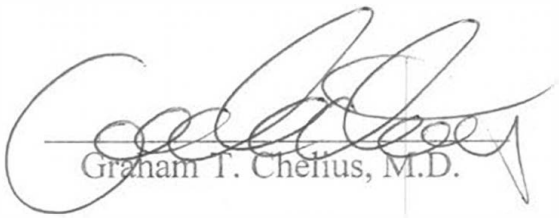
41. The bottom line is that, because of the REMS, I have been unable to provide my patients with essential health care that they need and that I am fully capable of providing. The REMS delays care, and forces patients to jump through hoops that are unnecessary, stigmatizing, and confusing. For some patients, the Mifeprex REMS makes abortion beyond reach. I greatly hope that Plaintiffs' motion for summary judgment once and for all lifts the unjustified REMS requirements from this safe, important drug, so that many other clinicians and I can provide it via prescription to our patients who need it.

42. I learned on April 13, 2021, that FDA has suspended the in-person dispensing requirement and authorized use of a mail-order pharmacy for providing patients with Mifeprex during the COVID-19 Public Health Emergency. I am exploring whether it will be possible for me to prescribe through a mail-order pharmacy under the special "supervision" requirement still imposed by FDA, and what kinds of contracts and/or billing practices may be necessary under FDA's non-enforcement guidance (which, of course, continues to treat Mifeprex differently than virtually all other drugs). I understand further that, even if I am able to take advantage of this in the short-term, this temporary allowance expires when the public health emergency ends. In short, there is an urgent need for

permanent relief through this litigation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 4/14/, 2021



Graham T. Chelius, M.D.

EXHIBIT 2

Declaration of Julie Amaon, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF JULIE AMAON, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Julie Amaon, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a board-certified family physician, licensed to practice in Minnesota, Texas, and Montana. I am trained to provide the full scope of family medicine with a focus on reproductive health care, including abortion.

3. Since July 1, 2020, I have been the Medical Director of Just The Pill, an organization founded in April of 2020 to improve access to sexual and reproductive health care for patients in rural Minnesota. To my knowledge, Just the Pill is the only mobile health center offering abortion care in the United States.

4. As a part of my practice, I prescribe mifepristone (brand name Mifeprex®) to patients seeking medication abortion. Because of restrictions imposed under the Food and Drug Administration ("FDA") Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, I cannot simply write a prescription for mifepristone for my patients to fill at a local or mail-order pharmacy, as they would for any other medication.

5. I can and do provide all counseling and assessment for eligible medication abortion patients in a telehealth visit, which FDA permits. FDA also permits my patients to take the medication at a location of their choice. But under the REMS, my patients have to travel in person to pick up their medication—a trip

that, for patients in rural Minnesota, can mean hours of travel each way and time away from family, and jobs. The challenge of arranging for lengthy travel and time away is often hugely burdensome for my patients, and, for some, means a delay of care beyond the point at which medication abortion is available to them or denial of access to abortion care altogether. In addition to these burdens, during the COVID-19 pandemic, the mifepristone REMS has subjected my patients and their families to needless risk of exposure to a deadly virus as they travel to pick up their medication.

6. I submit this declaration in support of the Plaintiffs' Motion for Summary Judgement in my individual capacity and not on behalf of Just The Pill or any other institution.

Limited Access to Abortion in Rural Minnesota

7. Minnesota's bricks-and-mortar abortion clinics are all located in three urban population centers: the Twin Cities, Duluth, and Rochester. According to the Guttmacher Institute in 2017, 61% of Minnesota women lived in a county lacking an abortion clinic.[1] Indeed, nearly half of the rural counties in Minnesota have no sexual or reproductive health clinics at all.[2]

[1] Jones RK, Witwer E & Jerman J, Guttmacher Inst. Abortion Incidence and Service Availability in the United States, 2017, at 17 (2019), https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017.

[2] Univ. of Minn. Healthy Youth Dev. Prevention Rsch. Ctr., 2019 Minnesota Adolescent Sexual

8. As a result, patients who reside in rural areas often must drive 3 or 4 hours *each* way to access abortion care, and sometimes longer in inclement weather during Minnesota's long winters. This travel requires patients to pay and arrange for transportation, time away from work, and child care, all of which can be costly and difficult. The expenses necessitated by this travel creates particularly weighty burdens for patients living with low incomes, which is the case for 75% of abortion patients.[3] As described below, for some patients the challenges they face in raising funds and arranging for travel and time away results in significant delays in their ability to access care and can prevent them from obtaining the abortion they seek.

COVID-19 and the Expansion of Telehealth Services

9. Just The Pill was established in the Spring of 2020, as the SARS-CoV-2 virus that causes COVID-19 spread through the United States, and access to abortion care in Minnesota became increasingly limited because of pandemic-related clinic closures and drastically reduced in-person care. At that time, the provision of health care in the United States was changing dramatically. Federal and state governments urged health care providers to use telemedicine to provide

Health Report 3 (2019), https://kstp.com/kstpImages/repository/cs/files/2019_ashr_final.pdf.

[3] Guttmacher Inst., Induced Abortion in the United States (2019), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states#.

care whenever possible to maximize patient access to health care while minimizing the risk of viral transmission associated with travel to health care facilities during the pandemic.

10. At that time, I was working in a family medicine clinic, and like other physicians throughout the country, my practice transformed from an almost entirely in-person practice to one in which a broad range of primary care was offered by telehealth. However, because of the REMS, medication abortion patients were still required to travel in person to a health care facility to pick up their mifepristone. For patients in rural Minnesota, this meant continuing to travel long distances to access care. Just The Pill was created with the goal of helping such patients reduce the burdens and risks of travel by offering care from a mobile health clinic that could bring services closer to the patients.

11. In the summer of 2020, as Just The Pill was raising the funds to pay for its mobile health clinic, a federal district court in Maryland entered an injunction suspending the mifepristone REMS in-person requirements for the duration of the COVID-19 Public Health Emergency ("PHE").[4] This meant that mifepristone prescribers could mail or deliver mifepristone to patients or arrange to have the medication sent from a mail-order pharmacy.[5] As a result, Just The Pill

[4] *Am. Coll. of Obstetricians & Gynecologists v. FDA* [hereinafter "*ACOG v. FDA*"], 472 F.Supp.3d 183 (D. Md. 2020).

[5] *Id.*; *ACOG v. FDA*, Civ. No. TDA-20-1320, 2020 WL 8167535 (D. Md. Aug. 19, 2020).

pivoted from its plan to treat patients from a mobile health clinic and, in October of 2020, began offering medication abortion care via telehealth to eligible patients throughout Minnesota and delivering their medication directly to them through a mail-order pharmacy. However, in January of this year, the U.S. Supreme Court issued a stay of the injunction, reinstating the mifepristone REMS in-person requirements.[6]

12. From October of 2020 until the Supreme Court reinstated the mifepristone REMS in-person requirements, Just The Pill provided medication abortion by telemedicine with delivery from a mail-order pharmacy to nearly 100 patients in Minnesota. During this period, patients would schedule a telehealth appointment with me, where we would discuss the patient's medical history and symptoms to permit me to assess whether they were eligible for a fully remote medication abortion. If their medical history and symptoms were consistent with a fully remote medication abortion, I would provide comprehensive counseling, just as I would at an in-person visit. This included discussing the medication abortion process and the risks, benefits and alternatives to a medication abortion; reviewing FDA's Patient Agreement for mifepristone; informing the patient about our 24-hour-a-day phone line in the event that they had any questions after the appointment; reading the Minnesota state-mandated information about abortion;

[6] *ACOG v. FDA*, 141 S. Ct. 578 (2021).

and answering any questions they might have, ensuring that they had all the information they needed to make an informed decision about their care. After answering any additional questions, I would ask if they consented to a medication abortion, and if so, document that consent in their medical record. I would then *again* review the instructions for how and when to take their medication, what the follow-up process was, and what they should do if they experienced any of the (very rare) complications associated with mifepristone.

13. Following the telehealth visit, I would direct the mail-order pharmacy with which I have a contract for shipping and dispensing mifepristone to send the patient a package containing the medications (mifepristone, misoprostol, and, if requested, anti-nausea medication and ibuprofen for their comfort), written instructions, the mifepristone medication guide, and our 24-hour telephone number. We tracked shipments and confirmed delivery to patients from the mail-order pharmacy; the process was efficient and effective. As with the medication abortion itself, the medical follow-up for the vast majority of patients was also completed remotely, using telephone or audio-video communications and an at-home pregnancy test. None of the nearly 100 patients we treated through this process experienced a serious complication.

14. Being able to obtain their abortion medications from a mail-order pharmacy, without an unnecessary in-person trip to a health clinic, was a huge

relief for my patients. It enabled them to end their pregnancies earlier and more safely, without the need to travel long distances, arrange for child care, and take time away and lose pay from much needed jobs—and without the risk of viral exposure that jeopardized their health and lives and that of their families for no medical purpose. In a survey during part of this time in which 45 patients participated, 16 told us that, without the ability to have a telehealth visit and have their medication delivered directly to them, they would have had to delay care for "significantly more than 2 weeks," and 2 already knew they would not have been able to access abortion care at all and would have been forced to carry their unwanted pregnancies to term.

Burdens and Risk for Patients Following Supreme Court Stay

15. After the Supreme Court reinstated the mifepristone REMS in-person requirements, Just The Pill began providing care from a mobile health clinic at locations throughout the State to help patients access care. We did all evaluation and counseling with our patients via telemedicine, but we could no longer have their medication shipped to them; instead, they had to travel to where our mobile clinic was located on a given day.

16. We attempted to drive our mobile health clinic to locations that would be most helpful for our patients. These are largely places with communities facing the greatest barriers to traveling for care—such as communities with high

concentrations of migrant farm workers; areas with high poverty rates; and communities hardest hit by the COVID-19 pandemic, including those with large concentrations of Black, Indigenous, and people of color, and one particular community with a widespread outbreak of COVID-19 among workers at a meat-processing plant. However, we are a small operation, able to travel only a few days a week to a few different places in a very large state. Even with our atypical (and highly labor intensive) care delivery model, our patients continued to suffer significant burdens and risks as a result of the travel necessitated by the REMS.

17. For example, I recently treated a patient who lived in far northern Minnesota—on the Canadian border. Based on her medical history and symptoms, she was eligible for a fully remote medication abortion. I had conducted a telehealth visit with her, but, because of the REMS, she had to travel in person to pick up her medication. She scheduled her appointment on a day when we would be driving the mobile health clinic to our farthest north destination—approximately 4 hours northwest of Minneapolis. Even so, this meant that the patient had to travel 2 hours each way to us. She did not have a car and the only way for her to get to us was by cab, which cost approximately $300. When she arrived, she quickly got out of the cab, ran to the mobile clinic, and then immediately turned around to go home with her medication. Fortunately, we were able to raise private funds for this patient to get the care she needed. She told me that had assistance not been

available to pay for her to take a cab to our mobile clinic (or had Just The Pill's mobile clinic not been available), there is no way she could have afforded to get to clinic and she would have had to carry her pregnancy to term. But for the REMS, this patient could have received her medication without ever leaving her home.

18. We recently treated a patient who had 3 children, no car, and would have had to travel 3 hours round-trip to get to the nearest bricks-and-mortar clinic offering abortion care. We were able to treat her by telemedicine, but she had no one to care for her children and was unable to arrange for transportation to pick up her medication even from our mobile health center. In order to help this patient, we drove the mobile health clinic and parked it a block from her home so that she could walk to our mobile clinic. This was an extremely unusual situation; we simply could not do that for every patient. However, if we had not done so for this patient, she would not have been able to have the abortion she sought. But for the REMS in-person requirement, we could have had the medication sent directly to her following her telehealth visit.

19. Another patient with 4 or 5 children at home was trying to arrange to travel to our mobile health clinic to pick up her medication. This patient lived a 5-hour round-trip car ride from the nearest bricks-and-mortar clinic offering abortion care. She had a car, but it was not reliable, even for the 1-hour drive to our mobile clinic. We offered financial assistance for a cab, but this patient could not take

advantage of it, because she could not fit all of her children in the cab. Her spouse was a long-distance truck driver who was on the road most of the time, and, since the patient was new to the area, she did not have anyone she could turn to for child care assistance. To help this patient, we were able to drive the mobile health clinic to her town; however, this meant a delay of more than a week before she could obtain care. But for the REMS, we could have had her medication delivered directly to her home without such delay.

20. I have had numerous patients who have had to cancel appointments at the last minute because they can't get time off work, find child care, or forgo other obligations with which this travel interferes, or because their travel arrangements have fallen through. For some of these patients, when they tried to reschedule, we had to tell them that they were no longer eligible for a medication abortion because they were beyond 10 weeks in pregnancy. When that happens, we refer them to other abortion providers who offer in-clinic procedures, but, since there are so few abortion clinics in the state, this generally means even lengthier and more costly travel, and therefore more delay. Given the challenges that prevent such patients from accessing even our mobile clinic, I feel certain that some were never able to make the journey to a brick-and-mortar clinic in one of Minnesota's urban centers and therefore were forced to continue their pregnancies and have a child. But for

the REMS, these patients could obtain care without delay by telemedicine and home delivery of medication.

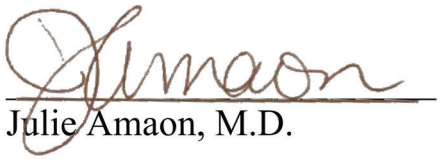
Barriers to Prescribing Mifepristone

21. Even though medication abortion could be safely provided in primary care and other health care settings throughout the state, the REMS requires health care providers to register as certified prescribers with the REMS program and stock mifepristone onsite for in-person dispensing. I have seen how these requirements prevent would-be mifepristone prescribers from providing this essential care to their patients. I know clinicians who would have prescribed mifepristone but were prevented from stocking and dispensing it onsite by others at the facilities in which they practice. For example, the family medicine clinic where I did my residency training was not permitted to stock mifepristone onsite because of opposition from someone at the institution. If it were not for the REMS, however, clinicians would have been able to send in mifepristone prescriptions to a pharmacy, as they do for virtually all other medications. Instead, because of the REMS, clinicians who practiced at the clinic could not provide mifepristone to their patients. The mifepristone REMS creates unnecessary barriers to the provision of care.

22. Earlier this week, FDA announced that it would suspend enforcement of the REMS in-person requirements during the COVID-19 PHE. This is

extremely good news for my patients, who now again have the opportunity to receive care by telehealth and have their medication delivered directly to them from a mail-order pharmacy. However, this non-enforcement policy is limited to the PHE: when the PHE ends, the REMS in-person requirements will again harm my patients as they have in the past.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on April 14, 2021.



Julie Amaon, M.D.

EXHIBIT 3

Declaration of Joey Banks, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF JOEY BANKS, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Joey Banks, M.D. declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a family medicine physician. I work at Blue Mountain Clinic in Missoula, Montana, where I have been providing care since 2011. I currently provide and train residents in reproductive health care, including abortion, at the Blue Mountain Clinic and also provide such care at a clinic in Tulsa, Oklahoma.

3. In addition, I serve as the Chief Medical Officer for Planned Parenthood of Montana, a position I have held since 2019. In this capacity, I supervise the medical staff at all Planned Parenthood sites statewide and also provide reproductive health care to patients.

4. In my practice I prescribe mifepristone (brand name Mifeprex®) to my patients both for pregnancy termination and in cases of pregnancy loss (where mifepristone assists in safely and efficiently completing the miscarriage). I have provided abortion and miscarriage care to patients for 20 years and, over the years, have provided such care to many people who lived in areas where care is difficult to obtain—including in Alaska, Maine, Montana, and, most recently, in Oklahoma.

5. I am a member of the National Abortion Federation, the American Academy of Family Physicians, and the Montana Academy of Family Physicians. I am also a member of the Society of Family Planning ("SFP"). I understand that SFP is a plaintiff in litigation challenging FDA's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, and write this declaration in support of SFP's Motion for Summary Judgment. I do so in my individual capacity and as an SFP member, and do not speak on behalf of Blue Mountain Clinic, Planned Parenthood, or any other institution.

6. Until a couple of years ago, Blue Mountain Clinic was the only clinic in Missoula where patients could access abortion care. The Blue Mountain Clinic is located near a perinatologist's office. A perinatologist is an obstetrician who specializes in maternal-fetal medicine and has special training in high-risk pregnancy care. Perinatologists sometimes use mifepristone to induce labor in late pregnancy.

7. The perinatologist near my clinic did not stock mifepristone, but occasionally wanted to administer it to his patients to induce labor in late pregnancy. Knowing that I stocked and provided mifepristone to my patients, in 2018 the perinatologist approached me about whether I would be amenable to his sending his patients to see me just to obtain the mifepristone, and then he would re-assume care after the patient left my clinic.

8. When I asked the perinatologist why he didn't stock mifepristone himself, he said it was because he was worried that by stocking mifepristone he would unwittingly be placed on a list of abortion providers. The perinatologist was aware of the history of violence and harassment by anti-abortion activists and was concerned that if the list of mifepristone prescribers required by the REMS were somehow made public, it would put him in danger.

9. The perinatologist was affiliated with and provides services at a local hospital in Missoula, Montana. When I asked why he didn't just ask the hospital to stock mifepristone in its formulary, he said that he did not want anyone in the hospital to presume he was pro-choice.

10. This is not the only instance in which I have encountered clinicians who are unwilling to stock mifepristone even though it would benefit their patients. For instance, since 2013, I have been providing reproductive health care training to family medicine residents at Blue Mountain Clinic. My training includes, among other things, medication abortion, procedural (sometimes called "surgical") abortion, and miscarriage management. For many

years, I have taught residents to treat patients seeking medication abortion with a regimen of 200mg of mifepristone followed by 800mg of misoprostol; and, since 2018, based on new, high-quality medical research, I also began teaching them this two-drug regimen for the medical management of miscarriages. Although both can be accomplished with misoprostol alone, evidence supports the two-drug regimen as the superior regimen.

11. On numerous occasions, I have been contacted by physicians I previously trained, telling me that the health care facility where they work does not stock mifepristone, and that they felt uncomfortable asking leadership at their health care facility to begin stocking mifepristone, or that they knew their clinic simply would not stock mifepristone. They all wanted to know whether they could still care for patients who sought a medication abortion or suffered a miscarriage, even without mifepristone. In light of these conversations, I now explain to the residents I train that if their health care facility does not stock mifepristone, they can consider prescribing misoprostol alone for either early abortion or miscarriage treatment, but that it is less effective and that the two-drug regimen, including mifepristone, is the superior regimen

12. In my experience, the mifepristone REMS is interfering with practitioners' provision of evidence-based medicine. Some clinicians fear professional repercussions if they try to persuade their colleagues to stock and dispense mifepristone onsite. And some are so concerned about the stigma and threat of violence surrounding the provision of abortion that they are unwilling to register their names and addresses with the mifepristone distributer, as required by the REMS. The prospect of this "abortion provider list" being leaked to the public is enough to prevent clinicians from providing what they deem the best medicine for their patients.

13. In sum, the mifepristone REMS prevents clinicians from providing solid evidence-based medicine due to the stigma and fear associated with having to register with the

drug manufacturer and stock the medication onsite.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on April 12, 2021.

Joey Banks, M.D.

EXHIBIT 4

Declaration of Jared Garrison-Jakel, M.D.

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Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF JARED GARRISON-JAKEL, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Jared Garrison-Jakel, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a board-certified family medicine and addiction medicine doctor in Guerneville, California, and a member of the California Academy of Family Physicians ("CAFP"). I understand that CAFP is a plaintiff in this litigation challenging the U.S. Food and Drug Administration's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex, and write in support of that litigation. The Mifeprex REMS causes injury to me and my patients. But for the REMS, I could and would provide Mifeprex to my patients.

3. I received my undergraduate degree from Pomona College in 2005, a Master's in Public Health from the University of California Berkeley in 2009, and my medical degree from the University of California Irvine School of Medicine in 2010. I subsequently completed an internship and residency in family medicine at Sutter Medical Center of Santa Rosa in California.

4. I am trained in both medication and surgical abortion and provided those services while in my residency at Sutter Medical Center of Santa Rosa.

5. Since 2013, I have practiced at Russian River Health Center in Guerneville, California ("Russian River"). I submit this declaration in my individual capacity and— besides CAFP—not on behalf of any institution with

which I am associated, including the health center.

6. Russian River is a federally qualified health center ("FQHC"). FQHCs offer primary health care services to low-income populations in medically underserved areas. Guerneville, where Russian River is located, is an economically depressed city with virtually no other health care facilities. Our health center is located about 30 minutes away from any other doctor's office.

7. Many of my patients have little access to transportation outside of the community where Russian River is located. This lack of transportation makes it difficult to access even urgent health care services. For example, I treated one patient who had a terrible cut in her hand—the laceration reached the tendon. I told this patient that she needed to see a hand surgeon due to the severity of the laceration, but the patient explained that such travel would be impossible for her. She told me, "Doc, either you fix it now or no one's fixing it."

8. As explained below, because of the REMS, medication abortion is not available in the health center where I work. As a result, I have had to turn away patients who need abortion care. The closest clinic that offers abortion services is a one-hour round-trip from our health center. Traveling such a distance is a significant impediment for the populations I serve, who generally struggle to afford and arrange for things like transportation and child care. And, making this journey may very well also require my patients to miss work, and therefore lose wages—

that is, if they can get time off work at all; at the low-wage jobs where my patients typically work, there is often no paid leave. The reality is that it can be difficult or impossible for my patients to overcome all of these barriers.

9. I am medically qualified to provide Mifeprex to my patients who request a medication abortion. The only reason why I am not able to do so is because of the requirement that I stock and dispense Mifeprex on site.

10. I am aware that at least one of my colleagues, who holds a position of authority at our institution, is opposed to abortion and would not consent to Mifeprex being stocked and dispensed in our health center. (For the same reason, we cannot provide surgical abortion services here.) However, I am also aware that this colleague would not interfere with my writing a prescription for Mifeprex in the privacy of my office for a patient to fill at a pharmacy—and there are two pharmacies very close to the health center where I work; one is only a block away. But for the REMS, I could and would provide medication abortion care to my patients (and would do so in compliance with all federal segregation guidelines for FQHCs that provide abortion services).

11. Because of the REMS, I have been unable to treat my patients in accordance with my medical judgment. Multiple patients have come to me with unwanted pregnancies at less than ten weeks, who requested—and were eligible for—medication abortions. However, because of the REMS, I had to deny them

this care—delaying their abortion, to the extent that they could obtain the abortion at all. Indeed, I am always reluctant to refer a patient to another health care facility, whether for abortion or any other medical service; given the financial challenges that my patients almost uniformly face, which are often compounded by other barriers and stressors (such as mental health disorders, substance use disorders, or homelessness), such a referral usually means that they will be significantly delayed in accessing medical care, or not obtain it at all.

12. There are three central concerns with delaying abortion care. First, if a patient is delayed past ten weeks of pregnancy, she typically will no longer be able to obtain a medication abortion and will instead need to have an in-office clinical procedure, which may be an inferior option given her circumstances. Second, while abortion is extremely safe, and far safer than remaining pregnant and carrying to term, the risk of complications increases as the pregnancy progresses. I can recall at least one patient who came to me at a point in pregnancy when she was still eligible for a medication abortion but, because I could not write her a prescription for Mifeprex, ended up having a more invasive and time-consuming second-trimester dilation and evacuation abortion procedure over a month later. Third, delaying a patient's abortion means that the patient stays pregnant longer, and thus must incur the serious risks and discomforts associated with pregnancy for longer.

13. Moreover, because of the REMS, at least one of my patients was prevented from having a desired abortion at all. This patient had a history of sexual trauma and struggled with substance use disorders. She was extremely distressed to learn that she was pregnant, and presented to me seeking a medication abortion. To add to the complications of her situation, she did not feel that she could disclose her desire for an abortion to her partner. I initially referred her to the nearest clinic providing first-trimester abortion services, but she was unable to make the journey to that clinic for her appointment. I saw her again in her second trimester, when she reiterated that she did not want to carry the pregnancy to term. At that point, I referred her to the nearest provider of second-trimester abortions, which is approximately three hours round-trip from Guerneville. I know that the care team at that facility worked diligently to support her in accessing abortion care, including trying to arrange transportation for her. Nevertheless, because of the many challenges in her life, she missed multiple appointments there as well. This patient ultimately ended up carrying the pregnancy to term. I have grave concerns about how this unintended pregnancy has affected her life; when I'd seen her, she communicated that the pregnancy had worsened her suffering around her sexual trauma history and medication dependency. Moreover, this patient did not obtain adequate prenatal care during her first or second trimesters because this was not a pregnancy she had intended to carry to term. Needless to say, denying this patient

the care she so desperately wanted and needed was not in accordance with my best medical judgment.

14. In short, the Mifeprex REMS has prevented me from fulfilling my personal, professional, and ethical obligations to provide my patients with the medical care they need, which I am qualified to and would otherwise provide.

15. I am aware that the FDA just announced that, for the remainder of the COVID-19 Public Health Emergency, it is suspending enforcement of the requirement that patients obtain Mifeprex in person at a health center and instead allowing patients to obtain their medication by mail or from a mail-order pharmacy acting under the supervision of a certified REMS prescriber. Although this is an important step in the right direction, even under this short-term policy, the FDA continues to treat Mifeprex differently than any other drug I prescribe. I am working to understand what this "supervision" requirement entails (such as with regard to billing) and determine whether or not I will be able to take advantage of this temporary policy shift. Regardless, a permanent fix is essential to ensure that my patients can access medication abortion care without facing needless, and sometimes insurmountable, hurdles.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on April 14th, 2021, in Guerneville, California.

Jared Garrison-Jakel, M.D.

EXHIBIT 5

Declaration of Erin King, M.D.

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IN THE UNITED STATES DISTRICT COURT
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Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF ERIN KING, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Erin King, M.D. declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a board-certified Obstetrician Gynecologist ("Ob-Gyn") licensed to practice in Illinois and Missouri. I treat patients principally at a general Ob-Gyn practice in St. Louis, Missouri, and at the Hope Clinic for Women ("Hope Clinic") in Granite City, Illinois, where I also serve as the Executive Director. I provide patients with the full scope of obstetric and gynecological care, including abortion care.

3. I am a member of the American College of Obstetricians and Gynecologists, the National Abortion Federation, and the Society of Family Planning ("SFP"). I understand that SFP is a plaintiff in this litigation challenging the Risk Evaluation and Mitigation Strategy ("REMS") that the Food and Drug Administration ("FDA") imposes for mifepristone (brand name Mifeprex®). I write this declaration in support of Plaintiffs' Motion for Summary Judgment, on my own behalf, and not on behalf of Hope Clinic or any other institution.

4. I am a certified prescriber under FDA's mifepristone REMS. I prescribe mifepristone as part of a medication abortion regimen and for patients seeking medical management of miscarriage. I also provide training in medication abortion and other abortion and reproductive health care.

5. I am aware of clinicians who would prescribe mifepristone for medication abortion and miscarriage care for their patients if they could send in a prescription to a local or mail-order pharmacy as they do with nearly all other medication. However, the mifepristone REMS—which requires clinicians to register as certified prescribers and to stock and dispense mifepristone in their offices—has prevented them from using mifepristone in their patient care. Physicians I have trained have often told me that they are unable to find employment with practices that are willing to stock mifepristone and, as a result, were not able to provide medication abortion or miscarriage care using mifepristone to their patients, though they would have been able to provide this care if they could simply write a prescription.

6. The mifepristone REMS also imposes significant burdens on my patients. Because of the REMS, my patients whom I can evaluate and counsel via telemedicine have had to travel unnecessarily to my clinic for their medication. They have had to find and pay for transportation and child care and take time away from jobs that pay by the hour or day. This is particularly burdensome for my many patients who live with low incomes and have to travel long distances, from rural parts of southern Illinois, to get to my clinic. In addition, during the COVID-19 pandemic, the REMS has put them and their families at needless risk for contracting a deadly virus as they travel in person to pick up medication that they

could otherwise safely receive by mail at home.

7. Last year, a federal district court in Maryland issued an injunction suspending the mifepristone REMS in-person requirements for medication abortion for the duration of the COVID-19 federal Public Health Emergency ("PHE").[1] The injunction permitted me to contract with a mail-order pharmacy to ship mifepristone to my eligible patients. That meant that, for my medication abortion patients who did not require in-person assessment, I could provide all counseling and assessment in a telehealth visit and then have the medication delivered directly to them from the mail-order pharmacy.

8. On the day we began offering patients the option to receive their prescription through the mail-order pharmacy, I treated a patient who had had an appointment to come to the clinic for a medication abortion but had had to cancel because she could not get time away from work and could not find anyone to stay with her children. She told me that she would have had to forgo an abortion altogether if we had not been able to offer her a telemedicine visit and delivery of her medication, because she did not think she would ever be able to make the arrangements necessary to get to the clinic in person. But, because the REMS in-person requirements were enjoined, she was able to have a safe abortion from the

[1] *Am. Coll. of Obstetricians & Gynecologists v. FDA* [hereinafter "*ACOG v. FDA*"], 472 F.Supp.3d 183 (D.Md. 2020); *ACOG v. FDA*, Civ. No. TDA-20-1320, 2020 WL 8167535 (D.Md., Aug. 19, 2020).

safety and privacy of her own home.

9. Unfortunately, however, the U.S. Supreme Court entered a stay of the injunction, reinstating the in-person requirements.[2] As a result, for the past three months I have again been forced to require patients seeking medication abortion care to travel to the clinic to pick up their medication.

10. This requirement imposes substantial burdens on my patients. Since the Supreme Court reinstated the REMS in-person requirements, I have seen numerous patients who needed no in-person assessment but nevertheless had to travel multiple hours, each way, to come to my clinic to pick up their medication. These patients have had to bear the costs and burdens of arranging travel, time away from work, and child care, when they could just as safely have obtained their prescription by mail and avoided all of these burdens.

11. Needing to make these arrangements and raise funds for this travel has often delayed my patients' care—sometimes beyond the point when they can have a medication abortion. I recently saw a patient who wanted a medication abortion but was 13 weeks pregnant and therefore had to have an in-clinic procedure. She was very upset, explaining that she had rescheduled her appointment numerous times because she could not arrange for travel or find someone to take care of her children—and during the pandemic, she could not

[2] *ACOG v. FDA*, 141 S. Ct. 578 (2021).

bring her children with her to our clinic, because we do not allow anyone other than the patient to enter in order to mitigate viral spread. But for the mifepristone REMS, I could have treated this patient in a telemedicine visit and had her medication delivered to her at home while she was still eligible for a medication abortion. This patient is not alone; I see patients every week with one variation or another of this story.

12. I am able to provide care entirely by telehealth for a wide array of other medical needs. For instance, I regularly use telehealth to diagnose, treat, and counsel patients regarding urinary tract infections, vaginitis, rashes, and contraception needs. In my practice, we also conduct prenatal and post-partum visits remotely. We can even examine a patient's sutures and evaluate how well the patient is healing after surgery in a telehealth visit. I can just as safely and effectively evaluate and comprehensively counsel eligible medication abortion patients in a telehealth visit. However, because of the REMS, my patients who require mifepristone have had to suffer needless burdens and risks that my patients who can obtain care entirely by telehealth are able to avoid.

13. Earlier this week, FDA announced that it would suspend enforcement of the REMS in-person requirements during the COVID-19 PHE. I am very pleased that my patients receiving care by telehealth can now have their medication delivered directly to them from a mail-order pharmacy without the

costs, risks, and burdens of a needless in-person trip. However, when the PHE ends and this non-enforcement policy expires, the REMS in-person requirements will again impose substantial burdens on my patients.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on April 14, 2021.

Erin King, M.D.

EXHIBIT 6

Declaration of
Charisse M. Loder, M.D., M.SC.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]
DECLARATION OF CHARISSE M. LODER, M.D., M.SC., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Charisse M. Loder, M.D., M.Sc., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am an obstetrician-gynecologist trained in abortion care and a member of the Society of Family Planning ("SFP"). I am a Clinical Assistant Professor of Obstetrics and Gynecology at the University of Michigan Medical School. My practice is located at the Women's Clinic at Von Voigtlander Women's Hospital in Ann Arbor, Michigan. I have also practiced as an obstetrician-gynecologist at Planned Parenthood in Ann Arbor.

3. I received my undergraduate degree from Cornell University in 2003, and my medical degree from Pennsylvania State University in 2011. I did my residency in Obstetrics and Gynecology at the University of Rochester, where I served as Chief Resident, and then completed a fellowship in Family Planning and received a Master of Science degree in Health and Health Care Research at the University of Michigan.

4. In my current practice, I provide a range of obstetrics and gynecology care, and specialize in miscarriage management, complex contraception and sterilization, and abortion care.

5. I submit this declaration in support of Plaintiffs' Motion for Summary Judgment. I do so only in my individual capacity and as a member of SFP, not on behalf of any institution with which I am affiliated.

6. Mifeprex is an important drug for the provision of abortion and miscarriage care. I advocated to make this medication available within the Women's Clinic in order to offer our patients the best possible care at our own institution, without having to refer them elsewhere.

7. While I am currently able to prescribe mifepristone to my patients, attempting to bring the Women's Clinic at the University of Michigan into compliance with the mifepristone (brand name Mifeprex®) Risk Evaluation and Mitigation Strategy ("REMS") was an extremely complicated process that took five years (and a substantial investment of time, resources, and professional capital by me and other colleagues). During these five years, my colleagues and I were forced to refer patients who needed medication abortion care to other institutions. When patients are referred elsewhere for abortion care, many experience delays or are even prevented from accessing this time-sensitive care. We were also unable to offer Mifeprex for miscarriage and second-trimester abortion care, even though Mifeprex enhances the efficacy of those treatments. There is absolutely no medical reason for FDA to impose these barriers to patients obtaining this safe and effective medication.

8. My involvement in the process of trying to make Mifeprex available at the University of Michigan began when I arrived at the University six years ago, in 2015. But conversations surrounding Mifeprex at the University of Michigan began seven years ago, in 2014. As of 2014, the only patients who could access mifepristone through the University of Michigan were those seeking treatment for Cushing's syndrome: University clinicians were able to prescribe mifepristone under the brand name Korlym, and the patients filled those prescriptions through a mail-order pharmacy. However, patients in need of mifepristone under the brand name Mifeprex, for reproductive health care, could not access the medication through any University provider.

9. As a first step, I had to get approval to add Mifeprex to the University's drug formulary from the University's Pharmacy and Therapeutics Committee ("the Committee"), which is composed of pharmacists and physicians from a variety of clinical specialties. As discussed above, I was not the first physician to attempt to do so; in 2014, other physicians had participated in multiple meetings with the Committee during which they advocated for adding Mifeprex to the formulary. Ultimately, these conversations stalled because those physicians were unable to invest the immense amounts of time required to move this process forward.

10. Between 2015 and 2016, I participated in approximately four Committee meetings relating to Mifeprex. To assist in the Committee's evaluation of Mifeprex, the Committee asked me and my colleagues to provide literature on Mifeprex's safety and indications for use, which we did. These meetings were each about an hour long, and I individually spent at least 20 additional hours researching and preparing presentations about Mifeprex's safety and efficacy, as well as writing guidelines for its use.

11. Finally, in 2016, the Committee approved Mifeprex for the University formulary. None of this would have been necessary—the Committee would not have been involved at all—if we could simply issue our patients a prescription to fill at a pharmacy instead of having to stock and dispense Mifeprex onsite.

12. But getting Mifeprex on our hospital's formulary still did not mean that University of Michigan clinicians could start prescribing Mifeprex to patients. Placing a drug "on formulary" means that the drug is approved for safe use by the hospital. But, in order to make Mifeprex available "in clinic" for patients, the University of Michigan first had to order and stock this medication. And it took me *three* more years of advocacy to achieve this second step.

13. In 2018, a pharmacist in the gynecology department suggested that I form a task force to develop protocols for Mifeprex use in-clinic because the process had stalled out. I believe that my colleague suggested that I create such a

task force in order to alleviate concerns throughout the University about how to comply with the Mifeprex REMS and to accelerate the process of actually stocking and dispensing Mifeprex. I have never heard of such a task force being formed for the introduction of other drugs or devices into University practice. For example, we frequently integrate new intrauterine contraceptive devices (IUDs) into our practice, and have never had to develop protocols about how to prescribe them. But I believed that without a physician champion and a committee specifically focused on this issue, Mifeprex would never be made available in our clinic.

14. Accordingly, I organized and created a multidisciplinary task force to develop various protocols for ordering, stocking, prescribing, and dispensing Mifeprex at the Women's Clinic. This task force is made up of gynecology and family medicine physicians, nurses, clinic managers, pharmacists, and electronic medical record (EMR) specialists. The task force was charged with finalizing protocols to address how Mifeprex is ordered, administered, and stored, as well as addressing safety and reimbursement concerns surrounding the storage and dispensing of Mifeprex at our clinic. In a large health care institution like ours, where every organizational decision requires approval from multiple stakeholders, none of these decisions were simple.

15. I first convened this task force in October 2018, and the task force met every six weeks until Mifeprex was available in clinic. The task force met for

about an hour each time—and that is only the tip of the iceberg. Since October 2018, I have spent at least 80 hours of my time preparing for and/or completing follow-up work relating to task force meetings (such as preparing education materials for clinical staff), as well as participating in numerous *non*-task force meetings with stakeholders to discuss protocols to ensure compliance with the REMS as we integrate Mifeprex into clinical practice. For instance, I met with EMR representatives to propose edits to our electronic medical records in order to track Mifeprex administration in patient records. I attended separate meetings with the Women's Clinic manager, insurance verification team, and billing team related to the University's financial and reimbursement concerns around the dispensing of Mifeprex onsite. And I consulted on strategies to communicate guidelines for Mifeprex administration with staff, including developing REMS-compliant protocols for nurses who may want to "opt-out" of any involvement in the dispensing of Mifeprex. If not for the REMS, I would not have had to involve all of these other clinicians and stakeholders within the University and invest so many hours of my time and professional resources into developing system-wide protocols to integrate Mifeprex into hospital practice. I would simply have written my patients a prescription.

16. The Mifeprex REMS also requires that clinicians register with the drug's distributor in order to become a certified prescriber. As an initial matter, this

requirement is medically unnecessary: Mifeprex is a safe and straightforward medication; the clinical competencies necessary to safely prescribe it are very common; and in general, and as a legal and ethical matter, my colleagues and I do not prescribe any treatment unless it is within our competency to do so. But the prescriber certification requirement also posed numerous obstacles to the provision of Mifeprex at the University of Michigan.

17. First, task force members raised concerns that the University would face legal liability if clinicians who were not acting pursuant to a REMS prescriber agreement prescribed this drug. We spent many meetings discussing protocols to prevent violations of the REMS.

18. Second, members of the task force were concerned about how to store Mifeprex to ensure that only certified prescribers can access it. As a result, the task force spent numerous meetings discussing how to properly secure the Mifeprex stock with locks, and how to determine which clinicians have access to the locked area.

19. Third, because of the prescriber certification requirement, the University of Michigan must update its EMR system and pharmacy database each time a physician registers as a certified provider. These updates are costly and require staff time. These systems must be updated constantly to alleviate a concern that someone will prescribe Mifeprex in violation of the REMS.

20. These organizational concerns related to prescriber certification stem not from any mistrust of physicians, but from concerns about compliance with the REMS.

21. I would never have been able to provide mifepristone to my patients if it were not for the tenacious advocacy and time commitment my colleagues and I invested into this effort. As it was, for more than five years, the REMS prevented me and all of my colleagues from providing that care to our patients and necessitated that we refer patients outside of the University of Michigan system. I know that many of my colleagues have had the same experience, because over the years, I have frequently been contacted by colleagues inquiring whether they were permitted to prescribe Mifeprex to their patients, and I had to tell them that—because of the REMS—the answer was no.

22. And my situation at the University of Michigan is by no means unique. I am regularly contacted by clinicians at other academic medical centers who are seeking advice on how to navigate the REMS in order to stock and dispense Mifeprex at their institutions.

23. Clinicians outside the University of Michigan have also shared with me that they have not integrated Mifeprex into their practice because they fear that completing the REMS prescriber certification requirement would place them on a registry of abortion providers and thus make them targets of anti-abortion

harassment or violence. If clinicians could simply write a prescription for Mifeprex without this obstacle and the other obstacles the REMS imposes, I believe that many more clinicians, in a wider swath of our state, would do so.

24. While abortion care is extremely safe, the risks associated with abortion increase as pregnancy advances. Therefore, delaying a patient's abortion care increases the risks she faces.

25. This delay also pushes patients past the point at which a medication abortion, or any abortion care, is available to them at all. When I worked at Planned Parenthood, I often saw patients who had been referred there by their primary provider because their provider does not provide medication abortion care. But, because of the delay caused by this referral, by the time these patients got to Planned Parenthood, they were frequently too far along in their pregnancies to be eligible for a medication abortion—even though they preferred that option and that option would have been most clinically suitable for them. Because of this delay, these patients were only eligible for aspiration or dilation and evacuation ("D&E") abortion, in-clinic procedures that are significantly more expensive than medication abortion. And some of these patients could not afford these more expensive in-clinic procedures and ultimately were unable to get an abortion at all.

26. My patients at Planned Parenthood frequently told me about the burdens they faced traveling to us for care: paying for transportation, arranging

child care, taking time (often unpaid) off from work, and more. Some of these patients traveled great distances: there are very few abortion providers in Northern Michigan or in Michigan's Upper Peninsula, and many of our patients traveled more than one and a half hours, and up to 10 hours, to obtain abortion care. Many of these patients shared that they could not access abortion care in their local community.

27. In addition to being an important part of safe, effective early abortion care, Mifeprex has other clinical indications, such as in medical management of pregnancy loss (miscarriage) and labor induction abortions during the second trimester. In both of these clinical circumstances, pretreatment with mifepristone reduces the length of the treatment and, as a result, reduces the risk of complications.

28. At the University of Michigan, my colleagues and I care for patients undergoing second-trimester labor induction in cases of pregnancy loss, or where the patient seeks abortion because of a diagnosis of fetal anomalies or due to significant risk to maternal health or life. During this process the patient experiences all the pain and physical consequences of labor. Clinicians often prescribe Mifeprex to patients going through this process, in order to make it easier and faster. When clinicians are unable to add Mifeprex to their treatment regimen,

many patients and their families suffer both emotional and physical tolls from longer labor inductions.

29. After five years of advocacy and hundreds of hours of advocacy by a few dedicated clinicians and stakeholders, Mifeprex finally became available onsite at the University of Michigan in late September 2019. But even now, the work continues: although Mifeprex is available at the Von Voigtlander Women's Hospital (where the Women's Clinic is located), I am still expending hours of effort to work to make Mifeprex available at our six OB/GYN outpatient sites, where clinicians continue to struggle to develop systems to stock and store Mifeprex consistent with the REMS. As a result, patients in those communities must travel longer distances (up to 40 miles round-trip) to get to our hospital for care, rather than being able to obtain a prescription for Mifeprex at their local outpatient site to then fill through a retail or mail-order pharmacy.

30. The Mifeprex REMS made this process extremely burdensome, requiring both an institutional champion (myself) willing to expend more than 80 hours of work and significant professional capital, and more institutional resources than I have seen for any other medication that has ever been made available in clinic at the University of Michigan. The five-year delay in Mifeprex's availability in clinic harmed patients.

hours of work and significant professional capital, and more institutional resources than I have seen for any other medication that has ever been made available in clinic at the University of Michigan. The five-year delay in Mifeprex's availability in clinic harmed patients.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 14, 2021.

Charisse M. Loder, M.D., M.Sc.

EXHIBIT 7

Declaration of Jane Roe, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF [redacted], M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

[redacted], M.D., a/k/a/ Jane Roe, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a Family Medicine doctor trained in abortion care. I live and practice in a rural area in the western United States, approximately 100 miles away from the nearest abortion clinic. I am seeking to proceed pseudonymously out of fear of being exposed—nationally and in my small, rural town—as an abortion provider. In light of the extreme harassment and violence, including murder, that has been perpetrated against abortion providers in the United States, I attempt to keep my provision of abortion care as private as possible; I am painfully aware that my primary practice does not have the safeguards in place that exist at the abortion clinics (several hours away) where I work part-time—bulletproof glass, violent intruder protocols, alarm button, separate entrance for providers, and so on. Moreover, given the significant abortion stigma in my community, I expect that I would lose many of my non-abortion patients at my primary practice if the fact of my abortion provision were widely known.

3. I am a member of Plaintiff Society of Family Planning, and I submit this declaration in support of Plaintiffs' Motion for Summary Judgment. I do so only in my individual capacity and not on behalf of any institution with which I am affiliated.

4. Attempting to comply with the Mifeprex REMS has been time-consuming, stressful, and professionally compromising. Because of the REMS, my ability to care for my patients in accordance with their needs and with my medical judgment has been conditioned on my seeking (and gaining) approval and assistance from countless individuals and committees within my health care institution. If not for the REMS, I could have simply written a prescription for Mifeprex for my patients to fill at a local or mail-order pharmacy, rather than having to mount a workplace lobbying campaign, and jeopardize my professional standing, in order to provide this safe medication onsite to my patients who need it.

5. I am a full-spectrum Family Medicine physician. In addition to my three years of residency, I completed a Family Medicine fellowship in obstetrics. I often care for three or four generations within a family—delivering a baby one day and caring for her grandmother the next. I perform a range of obstetric and gynecological services, such as cesarean sections, tubal ligations, leeps (which entails removing pre-cancerous lesions from the cervix), endometrial biopsies, and insertion and removal of intrauterine contraceptive devices.

6. I also provide miscarriage management, including by prescribing medications to evacuate the contents of a patient's uterus. When using medications to manage a miscarriage, it is the standard of care to use both Mifeprex and misoprostol, the same two drugs used in the FDA-approved medication abortion

regimen. Thus, as discussed further below, the restrictions on Mifeprex impact my ability to provide both abortion and miscarriage care.

7. I work at a hospital and affiliated clinic within a large health care system that includes multiple hospitals, each of which has one or more affiliated clinics. Many of my patients are low-income; virtually all are rural; and many travel to us from medically underserved areas in our state. Indeed, some of my patients live in areas where there are no roads—only snowmobile access in the winters.

8. Over the years, my colleagues and I have had multiple patients ask if we could provide a medication abortion, but—because we could not write them a prescription for Mifeprex to fill at a pharmacy—we had to refer all of these patients elsewhere for care. The nearest abortion clinic is a 200-mile round-trip, and some of these patients never made the journey, instead returning later for prenatal care. I recall one adolescent patient who told my colleague that she had repeatedly scheduled appointments at the abortion clinic, only to have to cancel multiple times because she simply could not make it there.

9. So, in February 2017, along with a few colleagues, I began the process of trying to get Mifeprex added to our hospital's formulary. The formulary is the list of medications approved for use by the pharmacy committees for our hospital and for our health care system, and then made available at our hospital for

dispensing or administering to patients. Based on conversations I had with colleagues about attitudes towards abortion at our institution, I concluded that there was a greater likelihood of my gaining approval to add Mifeprex to our formulary and dispense it in my office, rather than gaining approval to perform surgical abortion services in our operating room. That is because the latter would require the involvement of many clinicians, including nursing staff, certified scrub technicians, and anesthesia providers, and would thus require (at a minimum) approval from the CEO of the hospital and the departments overseeing each of those categories of clinicians, as well as the development of opt-out procedures for the supporting clinical staff.

10. Attempting to add Mifeprex to our formulary was a major undertaking. First, we had to obtain approval from the pharmacy committee at our hospital. Once that committee agreed to move forward with the process, we could elevate the request to the pharmacy committee for the entire health care system.

11. Over the next six months, we were delayed time and again in trying to get a decision from that system-level pharmacy committee—including being advised by a representative of the committee to delay raising the issue of Mifeprex until our request could undergo further "informal vetting," and then being bumped from the agenda for the committee's once-a-month meeting at least three times. In addition, the pharmacy committee representative insisted that *we* complete the

"new drug review" analysis for Mifeprex—a time-consuming assignment that, to my knowledge, is always completed by the system-level pharmacy committee, not by the hospital-level pharmacy committee or the individual physicians or pharmacists making the request. I believe this was demanded of us only because of the controversy and stigma surrounding abortion in our community, as in many places in this country.

12. Throughout the six months that we were slogging through this process—which would not have been necessary if not for the REMS—I was forced to turn away patients who needed my care. I know with certainty that, as a result, at least one of my patients was delayed past the point in pregnancy when she could obtain a medication abortion at all—which is available only up to 10 weeks of pregnancy—and had to travel 200 miles round-trip to have a surgical abortion instead. While abortion is one of the safest procedures in modern American medicine, and far safer for a woman than remaining pregnant and carrying to term, the risks associated with abortion increase as pregnancy advances. Thus, delaying a woman's abortion care increases the risks she faces.

13. It is inconsistent with both my medical judgment and my deeply held values to deny a patient's urgent request for time-sensitive medical care that I am qualified to provide—but that is exactly what the REMS required of me.

14. In September 2017, I was contacted by the Chief Medical Officer of

our health care system, who had apparently been informed of my request. To my knowledge, it is very unusual for the CMO to be involved in a formulary request, and I assume that my request was only elevated to this very high level because of the controversy surrounding abortion. He proposed a possible strategy to enable me to provide Mifeprex to my patients while avoiding the conflict that he expected would result from a system-wide debate on this question: namely, that I would prescribe and dispense Mifeprex as a "non-formulary drug," which the policy defines as "[a]n agent, which has not been reviewed by the [pharmacy committee] or has been reviewed and denied admission to the formulary."

15. This was a highly unusual application of our policy on non-formulary drugs, which to my knowledge is typically invoked in situations where patients admitted to our hospital need to continue a pre-established medication regimen for the short period of time that they are admitted. The policy on non-formulary drugs also expressly provides that usage of such medications will be "tracked and routinely reviewed . . . to evaluate appropriateness" by the system-level pharmacy committee—the very same committee that this strategy was designed to avoid, given the expectation of conflict over the abortion issue. Classifying Mifeprex as a non-formulary drug to be "tracked and routinely reviewed" meant that I had to continue to expend time, and put my professional reputation on the line, having discussions with leadership at my institution regarding my Mifeprex use. And, of

course, this designation meant that I could suddenly lose the ability to provide this care to my patients.

16. After gaining this temporary, precarious approval to stock and dispense Mifeprex on-site as a non-formulary drug, I next had to sign up with Danco (the manufacturer of Mifeprex) as a certified prescriber and set up an account with the drug distribution company. This was a significant ordeal in and of itself, further delaying my ability to care for my patients by approximately two months. I completed as much of the paperwork myself as I could, but setting up an account requires information (including on billing and shipping) that, as a doctor within a large health care institution, I do not have. This meant that I had to involve yet another colleague in the process—my Practice Administrator, who oversees finances, staffing, and other significant matters in our practice—and then repeatedly bother that person, who I know to be personally opposed to abortion, until it got done. If not for the REMS, I would not have had to compromise this important professional relationship in this manner.

17. I believe that the REMS has harmed my reputation among some of my colleagues by necessitating that I engage in an internal lobbying campaign to try to make Mifeprex available onsite, and necessitating the involvement of additional members of our staff in this care. For instance, I was informed about a senior leadership meeting at which a colleague raised as a "concern" that I was working

to make Mifeprex available at our facility (mentioning me by name).

18. *None* of this would have been necessary if I could simply write a prescription for Mifeprex for my patient to fill at a retail pharmacy, as I can do for virtually every other prescription drug. My colleagues do not have to expend such time and resources, or jeopardize their professional reputations, in order to prescribe other medications that are equally or less safe than Mifeprex.

19. Earlier in 2019, our health care system finally approved Mifeprex as a formulary drug. But this was no quick fix: ordering, stocking, and dispensing the medication remains a complicated, multi-stage process involving numerous staff members across our health care system. To begin, one provider from each individual clinic or hospital wishing to prescribe Mifeprex must register with the "buyer" for our health care system's central pharmacy. This entails attesting that they will oversee the prescription and dispensing of Mifeprex at their clinic or hospital site; completing the necessary materials for Danco; determining how many doses to order; and all of the correspondence and paperwork this necessitates. The central pharmacy then orders the medication to be stocked at the specific clinic or hospital.

20. In the Family Medicine clinic where I work, Mifeprex is stored under lock in our medication stock room, where we keep vaccines and other medications administered in the clinic (typically drugs administered by injection, or basic

painkillers like ibuprofen). When one of the medical assistants who works in my clinic sees that I have entered an order for Mifeprex, she goes into the medication stock room to obtain the pill and complete the special Mifeprex log, noting the serial number of the package (as required by the REMS) as well as the two-part patient ID (typically, the patient's medical records number and date of birth).

21. Having to comply with the REMS thus dramatically increases the number of people in our health care system who must be involved in the provision of Mifeprex. In addition to posing logistical complications, this heightens the risk of a violation of patient confidentiality—and perpetually threatens that a single individual who opposes abortion could delay or derail the process. By contrast, if not for the REMS, I could just electronically submit the prescription order to a pharmacy of my patient's choice and no one else would have to be involved.

22. Notably, formulary drugs are still subject to "annual" review by the system-level pharmacy committee (as compared to the "routine" review for non-formulary drugs)—which means that availability at our hospital is still subject to debate every year by a committee, the members of which change on a regular basis. My ability to include Mifeprex within my practice, and my patients' access to this vital care, remains precarious.

23. The Mifeprex REMS also requires me to provide my patients with and discuss, and for us each to sign, a "Patient Agreement Form" containing medical

information about Mifeprex dated to March 2016. This is not merely unnecessary from an informed consent perspective—it actively *undermines* my informed consent process by forcing me to discuss with my patients information that is inconsistent with my clinical approach and increasingly out-of-step with the research on Mifeprex as science moves forward. For instance, the form requires the patient's signature that, "[i]f my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy." However, I (like many clinicians) treat the small percentage of patients whose pregnancies continue following use of the Mifeprex and misoprostol regimen with additional medication doses in the first instance, not surgery. This is well within the standard of care, yet not reflected in the form—to the contrary, the form suggests to patients that surgery is the *only* option in such a case. Moreover, the statement that "the treatment will not work . . . . in about 2 to 7 out of 100 women" is misleading and not how I counsel my patients about the expected efficacy of the treatment: while in some small number of cases, the regimen listed on the label will not fully complete the abortion, the treatment may very well still work – after, for instance, an additional dosage of misoprostol.

24. The Form is particularly ill-suited for my patients to whom I am prescribing Mifeprex as part of miscarriage management, as has become the standard of care. The Form does not describe the clinical circumstances of patients

experiencing pregnancy loss, and can be confusing and distressing for them. Nevertheless, because of the REMS, I still must have these patients sign the Form before I can prescribe them Mifeprex. For all of these reasons, the Patient Agreement Form interferes with my ability to practice my profession in accordance with my medical judgment.

25. I hope that more clinicians within our health care system will begin providing Mifeprex at their own hospitals and clinics as well, and thus continue to expand access to this safe and effective medication. I have had numerous conversations with like-minded colleagues to that end, including giving them advice about navigating the multi-step, time-consuming process I described above to register with both our health care system and with Danco as a prescriber and then to actually get the medication onsite. Unfortunately, these logistical hurdles caused by the REMS have proven to be a significant deterrent, and there are still only a handful of us in the health care system who prescribe Mifeprex, either for abortion care or for miscarriage management.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in [redacted], on [redacted], 2021.

[redacted]

[redacted], M.D., a/k/a Jane Roe, M.D.

EXHIBIT 8

Declaration of Diana M. Pearce, Ph.D.
& Pearce Decl. Appendix

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF DIANA M. PEARCE, PH.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Diana M. Pearce, Ph.D., declares and states as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I provide the following facts and opinions as an expert in the field of Sociology, specifically specializing in poverty, women's welfare, and women studies in the United States. I hold an M.S.W. and a joint Ph.D. in Social Work and Social Science (Sociology) from the University of Michigan. I am currently the Scholar in Residence at the Center for Women's Welfare at the School of Social Work at the University of Washington, after serving as the Founder and Director of the Center for 18 years. For more than two decades, I have been on the faculty of the School of Social Work as a Senior Lecturer (now Senior Lecturer Emerita), as well as an affiliate of the Gender, Women and Sexuality Studies department and the West Coast Poverty Center, all at the University of Washington. For over 40 years, I have conducted research and published on the topics of poverty and women's welfare in peer-reviewed sociology and poverty journals. Most famously, I coined the term "the feminization of poverty,"[1] which became one of the ten themes of the Beijing Conference on Women in 1995, as well as the subject of countless articles and books.

[1] Diana M. Pearce, *The Feminization of Poverty: Women, Work and Welfare*, 11 Urb. & Soc. Change Rev. 28 (1978).

I have also authored numerous reports, including for the U.S. Department of Labor and the U.S. Civil Rights Commission.

3. Since 1996, I have been the creator and principal investigator of the Self-Sufficiency Standard (the "Standard"), which measures the amount of income necessary for different family types to meet basic needs without public subsidies or private/informal assistance. Since then the Standard has been calculated for 41 states.[2]

4. I have presented my research on poverty at numerous professional conferences and governmental briefings, including presentations to the U.S. Department of Health and Human Services and the U.S. House of Representatives. I also testified twelve times before the U.S. Congress. I have received various awards for my work and research, including:

- National Association of Social Workers, Presidential Award for Leadership in Research (presented at NASW Conference, The Feminization of Poverty Revisited) (2013)
- Wider Opportunities for Women, Setting the Standard (Lifetime Achievement) Award (2003)
- Workforce Development Council of Seattle-King County, for Visionary Research on Family Self-Sufficiency (2003)
- Society for Applied Sociology, Sociological Practice Award (2003)

[2] For all data and reports relating to and a general explanation of the Standard, see generally Self-Sufficiency Standard, http://www.selfsufficiencystandard.org/ (last visited Apr. 7, 2021).

5. A true and correct copy of my curriculum vitae is attached as Exhibit H-1 to this declaration.

II. THE IMPACT OF THE RISK EVALUATION AND MITIGATION STRATEGY (REMS) FOR MIFEPREX ON WOMEN SEEKING ABORTION CARE

6. I have been asked to evaluate the impact of the Mifeprex REMS on women in the United States seeking abortion care.[3] I understand that under the Mifeprex REMS, a patient cannot obtain the medication by prescription at a retail pharmacy or by mail; they must receive it at a clinic, medical office, or hospital from a clinician who has prearranged to stock and dispense Mifeprex. I understand that these requirements deter or prevent a significant number of health care providers, such as Dr. Graham Chelius on Kaua‘i, from prescribing medication abortion, and, as a result, some patients have to travel further distances or make an entirely unnecessary trip in order to access time-sensitive abortion care. I understand further that the REMS prevents medication abortion patients who have been evaluated and counseled via telemedicine from picking up their prescription at their local pharmacy or obtaining their mifepristone prescription by mail without even having to leave home, forcing such patients instead to make a trip to a REMS-certified provider just to pick up the pill and sign a form.

[3] I use “women” here as a shorthand for patients who need abortion care, but note that patients who are gender non-binary or transgender also utilize these services.

7. Data demonstrate that the overwhelming majority of abortion patients are low-income and struggle to make ends meet. As an expert in poverty and women's welfare who has studied the barriers that affect low-income women's access to health care, I know that low-income people find it extremely difficult just to afford their basic household needs, let alone unplanned emergency expenses like abortion. In my expert opinion, by requiring patients to make additional and/or lengthier trips to get a medication abortion, the Mifeprex REMS increases the costs and logistical burdens of accessing care—including missed work, transportation and child care costs—to such a degree that they significantly delay or entirely prevent women from accessing abortion care. Even for those who are ultimately able to access care, the resources and other hurdles that the REMS force women to navigate often require significant sacrifices for patients and their families that threaten patients' privacy and economic stability, including by jeopardizing their employment or housing, forcing patients to forgo other necessary expenses like food or other medical care, and increasing the risk of domestic violence.

A. Many Abortion Patients Cannot Afford to Meet Their Basic Needs.

8. The vast majority of women seeking abortion care have low incomes. In 2014, the most recent year for which data are available, half (49%) of women seeking abortions in the United States had incomes at or below the U.S. Official Poverty Measure (OPM), which for 2014 was $11,670 annually for a single person

or $19,790 for a family of three (in the contiguous U.S.).[4] Another quarter (26%) of U.S. abortion patients had incomes between 100 and 200% of the OPM in 2014.[5] In other words, based on the OPM, three out of four abortion patients are poor or very low-income.[6]

9. But it is likely that this statistic actually undercounts the percentage of abortion patients with inadequate income to meet their basic needs, because the OPM is based on a flawed and outdated methodology and set of assumptions. The OPM was developed decades ago and assumes that a family's total budget is three times what they spend on food—reflecting average American family expenditure patterns of the mid-1950s. However, household expenditure patterns have changed significantly since then. For instance, the cost of food has increased much less over

[4] Jenna Jerman, Rachel K. Jones & Tsuyoshi Onda, Guttmacher Inst., Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008 1, 7 (2016), https://www.guttmacher.org/report/characteristics-us-abortion-patients-2014; *Prior HHS Poverty Guidelines and Federal Register References*, U.S. Dep't of Health & Hum. Servs., https://aspe.hhs.gov/prior-hhs-poverty-guidelines-and-federal-register-references (last visited April 7, 2021). For 2021, the amounts are $12,880 for a single person and $21,960 for a family of three. *2021 Poverty Guidelines*, U.S. Dep't of Health & Hum. Servs.: ASPE (last updated Jan. 26, 2021), https://aspe.hhs.gov/2021-poverty-guidelines.

[5] Jerman, Jones & Onda, *supra* note 4, at 1, 7.

[6] *Id.* Because these statistics are drawn from surveys of patients who received an abortion, they do not account for poor or low-income patients who wanted to have an abortion but were prevented from accessing one because of financial or other barriers to access. *Cf., e.g.*, Sarah C.M. Roberts et al., *Out-of-Pocket Costs and Insurance Coverage for Abortion in the United States*, 24 Women's Health Issues e211, e215 (2014), https://www.sciencedirect.com/science/article/abs/pii/S1049386714000048 (in longitudinal study of abortion patients at 30 facilities across the country, more than half reported that the need to raise money delayed access to care).

the past decades than almost all other basic expenses, while other costs have increased substantially (housing, health care, taxes). Moreover, the OPM does not account for geographic variation in costs or for variations in family type (such as by children's ages), and it does not explicitly reflect basic needs like child care, taxes, health care, and transportation.[7]

10. A more accurate measure of income inadequacy is the Self-Sufficiency Standard, which my colleagues and I first developed two decades ago to address gaps and deficiencies in the federal poverty measures. The Self-Sufficiency Standard describes the minimally adequate income that a family of a certain composition in a given place needs to meet their basic needs, without public or private assistance. It is tailored to reflect the minimum actual costs of housing, child care, food, transportation, health care, miscellaneous expenses, taxes, and tax credits for 719 family types in every county in a given state. The Standard additionally reflects cost

[7] Increasing recognition of the OPM's shortcomings led Congress in the 1990s to direct the National Academies of Sciences, Engineering and Medicine to undertake a wide-ranging study of the measure. *See* Nat'l Rsch. Council, Measuring Poverty: A New Approach xv, 2–3 (Constance F. Citro & Robert T. Michael, eds. 1995), https://www.nap.edu/download/4759#. The study and resulting report spurred a number of experimental measures piloted by the U.S. Census Bureau, and, in 2010, the Bureau adopted the Supplemental Poverty Measure (SPM). *See* Liana Fox, U.S. Census Bureau, The Supplemental Poverty Measure: 2019 (2020), https://www.census.gov/library/publications/2020/demo/p60-272.html. Although the SPM addresses some of the problems with the OPM, such as varying housing costs by Census region, it does not consider the substantial variation in housing costs within the four Census regions, and it either fails to or inadequately addresses the other flaws discussed above. In particular, the SPM methodology does not address the most serious shortcoming of the OPM— that it seriously underestimates the total cost of basic needs—and thus like the OPM, the SPM is likewise much too low, everywhere and for every family type.

differentials due to the age of children; thus, families with children below school age requiring full-time child care will have a higher Standard than those with older or no children. Whenever possible, the amount for a given need is based on the amount of financial assistance that the government (federal or state) has deemed minimally adequate for that basic need (such as housing, child care, or food expenses).[8]

11. We have found that a substantial percentage of people across the country—and far more than are captured by the OPM—do not have incomes sufficient to meet their basic needs.[9] (This is true even though the vast majority of households with incomes below the Standard have at least one worker in them.[10]) The Standard is higher than the OPM in every jurisdiction for which we have

[8] For housing, the Standard uses the U.S. Department of Housing and Urban Development Fair Market Rents, which set the maximum rent allowed for Section 8 voucher (housing assistance) recipients; for child care costs, the Standard uses the maximum amount set by the state for reimbursement for those receiving child care assistance (minus child care copayments); and for food costs, the Standard uses the U.S. Department of Agriculture's "Low-Cost" Food Plan, which only covers the cost of basic groceries, with no allowance for any take-out or restaurant food. L. Manzer & A. Kucklick, Ctr. for Women's Welfare, Technical Brief: The Self-Sufficiency Standard 2021 Update (2021) (available upon request from the Center for Women's Welfare, University of Washington School of Social Work, www.selfsufficiencystandard.org).

[9] When calculating income inadequacy compared to the Standard, we consider all cash resources available to a household, including cash assistance, such as Temporary Assistance for Needy Families (TANF) or Supplemental Security Income (SSI). It should be noted, however, that the income limits for means-tested cash assistance are very low (often near or even below the OPM), and thus are never sufficient to bring a family up to their Self-Sufficiency Standard.

[10] *See, e.g.*, Diana M. Pearce, Ctr. for Women's Welfare, Overlooked and Undercounted 2018: Struggling to Make Ends Meet in Colorado, at vi (2018), http://www.selfsufficiencystandard.org/sites/default/files/selfsuff/docs/CO18_Demo_Web.pdf.

calculated it—sometimes significantly higher.[11] This is especially true for families—which is notable here since, nationwide, about 60% of women seeking an abortion have at least one child.[12]

12. In fact, the Self-Sufficiency Standard for a family consisting of one adult and one infant exceeds *200% of the OPM* in 92% of counties in the 31 states for which we have current Standard data and in every single county in 20 states. And the gaps are similarly stark for other family types.[13] In other words, given that the Standard is a bare-bones budget, it is clear that in the vast majority of counties in most states, abortion patients with incomes living up to 200% of OPM still lack the minimum income necessary to afford even their basic household needs.

13. My research in numerous states to determine the characteristics of households most likely to have income below the Self-Sufficiency Standard further reinforces the existing data showing that most abortion patients struggle to make ends meet. As noted, a majority of abortion patients are mothers,[14] and

[11] The states with current Standard data included in this analysis are: AL, AZ, CA, CO, CT, FL, GA, HI, IL, IN, KS, MA, MD, MI, MN, MO, NC, NJ, NV, NY, OK, OR, PA, SC, TN, TX, UT, VA, WA, WI, and WY. Data on file with the author.

[12] *Abortion Surveillance — United States, 2018*, Ctrs. for Disease Control & Prevention, at Table 7 [hereinafter "*CDC Abortion Surveillance*"], https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T7_down (last updated Nov. 7, 2020).

[13] For a family of one adult and one preschooler, the Standard exceeds 200% of the OPM in 88% of counties; for a family with one adult, one preschooler, and one school-aged child, in 83% of counties; and, for a family with two adults, one preschooler, and one school-aged child, in 84% of counties.

[14] *CDC Abortion Surveillance*, *supra* note 12, Table 7.

approximately 85% are unmarried.[15] Moreover, 60% identify as people of color, including 53% identifying as Black or Hispanic.[16] My colleagues and I have uniformly found that these are the very populations that are statistically more likely than other demographic groups to live below the Standard.

14. For example, the percentage of Black households with incomes below the Standard is on average double the percentage of white households with incomes below the Standard; the percentage of Latinx households is 2.5 times the percentage of white households; and the percentage of single-mother families with incomes below the Standard is 2.2 times that of married couples with children.[17] This is particularly true for single mothers of color: on average, almost three out of four (74%) Black single mothers, and almost four out of five (79%) Latina single mothers, have incomes below the Standard.[18]

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[15] *Id.* at Table 6, https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T6_down.

[16] *Id.* at Table 5, https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T5_down; *see also* Jerman, Jones & Onda, *supra* note 4, at 1, 5.

[17] Based on an analysis of Standard data and demographic reports for California (2019), Colorado (2016), Connecticut (2017), Maryland (2015), New York City (2019), New York State (2019), Pennsylvania (2017), Washington (2013), and Wyoming (2010–2014). Data on file with the author and/or available on the Standard website, in individual reports. *See Self-Sufficiency Standard by State*, Self Sufficiency Standard, http://www.selfsufficiencystandard.org/self-sufficiency-standard-state (last visited Apr. 8, 2021); *Research and Resources: Demographic Reports*, Self Sufficiency Standard, http://www.selfsufficiencystandard.org/node/30 (last visited Apr. 8, 2021).

[18] In every state for which we have performed these demographic analyses, at least 65% of Black single mothers and 74% of Latina single mothers had incomes below the Standard, compared to an average of 52% of white single mothers. See resources listed above, *supra* note 17.

15. To further illustrate this concept, consider Kaua'i. On that island, where Dr. Chelius's patients live, the 2020 Self-Sufficiency Standard—the *minimum* income necessary for basic subsistence, based largely on government reimbursement rates—for a single adult caring for one school-aged child and one preschooler was nearly 1.75 times the median household income for single-mother households in Kaua'i, and more than triple the 2020 OPM for a family of three.[19] For a single adult caring for one infant, the Standard was 1.8 times higher than the median income for single mothers in Kaua'i, and more than four times the 2020 OPM for a family of two.[20] Thus, many single-mother households in Kaua'i that would not be classified as poor or low-income according to the OPM are in fact struggling to afford basic household needs.

16. Kaua'i is not an outlier. I analyzed the monthly basic needs budget for families with one adult and one preschooler in the least expensive county, median county, and county with the largest city in eight representative states across the

[19] *Compare Hawaii Self-Sufficiency Standard Table, 2020*, at By County tab, Table 3, cell L71 (2020) [hereinafter "*Hawaii Standard 2020*"], http://www.selfsufficiencystandard.org/node/50 (Self-Sufficiency Standard of $69,224), *with* U.S. Census Bureau, *Table S1903: Median Income in the Last 12 Months*, https://data.census.gov/cedsci/table?q=S1903&tid=ACSST1Y2019.S1903 (filter by "Browse Filters: Geography," "Geography: County," "Within (State): Hawaii," and select "Kauai County, Hawaii) (last visited April 7, 2021) (median income of $39,422 for "Female householder, no spouse present" and "With own children under 18 years"), *and 2020 Poverty Guidelines*, U.S. Dep't of Health & Hum. Servs.: ASPE (last updated Jan. 21, 2020), https://aspe.hhs.gov/2020-poverty-guidelines (2020 OPM of $21,720).

[20] *Compare Hawaii Standard 2020*, *supra* note 19, at By County tab, Table 3, cell C71 (Self-Sufficiency Standard of $70,788), *with* U.S. Census Bureau, *Table S1903*, *supra* note 19 (median income of $39,422), *and 2020 Poverty Guidelines*, *supra* note 19 (2020 OPM of $17,240).

country, all of which have statewide poverty rates (according to the OPM) similar to either the national average or the average for their geographic region.[21] In every county in every state considered in this analysis, a full-time minimum wage worker[22] is unable to afford the minimum needs for their family. In all eight states, one adult with a preschool-aged child in the least expensive county in the state (*i.e.*, the county with the *lowest* Standard) needs at least 36% more than a full-time minimum wage income (Santa Cruz County, AZ) and as much as two or more times the minimum wage (Uvalde County, TX, and Person County, NC), just to afford their family's basic needs. For those living in the largest city in each of these states, the deficit is even more substantial: in Chicago (Cook County, IL), a single mother with a preschooler needs to earn almost twice the minimum wage, while in Charlotte, NC (Mecklenburg County), she needs to earn at least 3.6 times the minimum wage, just to meet her basic needs. These families are already forced to make sacrifices or economic trade-offs just to scrape by; *any* added expense, no matter how small, can be destabilizing, potentially forcing them to forgo basic needs like food, rent, or

[21] States used in this analysis are those (a) with statewide poverty rates closest to the national rate or to the average rate for states in their Census region, based on data from the U.S. Census Bureau, and (b) for which current Self-Sufficiency Standard data (2021) was available. *See* Exhibit H-2 (summarizing Standard data for all 8 states).

[22] The Standard assumes full-time work (40 hours per week). Thus, I am evaluating whether full-time work at the state (or local) minimum wage will be enough to meet the cost of basic needs in the Standard for this family type in each place.

medical care.[23]

17. Key economic trends indicate that American families may be facing even more challenges in the future. For example, in every state in which my colleagues and I have tracked the Standard over the last two decades, the cost of basic needs has been rising faster than income, even during the Great Recession and the subsequent Recovery.[24] In addition, the economic precarity of many working families across the country has only been amplified by the current economic recession relating to the COVID pandemic. While the data showing the full extent of the economic impact of the pandemic is not yet available, and uncertainty remains due to new surges in COVID cases, the widespread job losses and staggeringly high rates of unemployment experienced so far already have taken their toll, with large

[23] For many families, public assistance will be inadequate to fill these gaps. For example, as its name suggests, the Temporary Assistance for Needy Families Program (TANF) is not designed to be an ongoing source of income for working families; although work is required to maintain eligibility, even working part-time is likely to result in an income too high to maintain eligibility for TANF. And while in-kind benefits such as SNAP (food stamps), child care assistance, and housing assistance are meant to help low-wage workers, only a minority of eligible families actually receive those benefits. *See, e.g.*, Gov't Accountability Office, Child Care: Subsidy Eligibility and Receipt, and Wait Lists – Briefing to Senate Comm. on Health, Educ., Labor & Pensions and House Comm. on Educ. & Labor, GAO-21-245R, at 12 (2020), https://www.gao.gov/assets/gao-21-245r.pdf (only 14% of children eligible for child care assistance under federal standards, and only 22% of those eligible under state rules, actually receive such assistance in an average month); G.T. Kingsley, Urban Institute, Trends in Housing Problems and Federal Housing Assistance3 (2017), https://www.urban.org/sites/default/files/publication/94146/trends-in-housing-problems-and-federal-housing-assistance.pdf (only about one in five low-income renters with housing needs received assistance in 2015).

[24] For example, see Standard Reports for Colorado, Connecticut, Indiana, Maryland, Michigan, New York, New York City, North Carolina, Ohio, Oregon, South Carolina, Washington, Wisconsin, and Wyoming, all available at *Self-Sufficiency Standard by State*, *supra* note 17.

numbers of families citing serious economic impacts and concerns for the future.[25] These losses have disproportionately affected single mothers, particularly women of color, and other households that had inadequate income to meet their basic needs even before the recession.[26]

18. In sum, in considering the impact of the Mifeprex REMS on access to abortion nationwide, it is important to recognize that the vast majority of abortion patients—likely even *more* than the 75% of patients with incomes at or below 200% OPM—are already unable to afford their and their families' basic needs. For these patients, the unexpected, emergency expenses associated with traveling for abortion care—whether to another county, city, or state, or even to a second local health care facility—presents a serious hardship or is entirely impossible.

B. The Mifeprex REMS Imposes Significant Costs and Burdens on Medication Abortion Patients.

19. Abortion access is very limited in the United States. Approximately 90

[25] J. Horowitz et al., *A Year Into the Pandemic, Long-Term Financial Impact Weighs Heavily on Many Americans*, Pew Rsch. (Mar. 5, 2021), https://www.pewresearch.org/social-trends/2021/03/05/a-year-into-the-pandemic-long-term-financial-impact-weighs-heavily-on-many-americans/ (finding that 40% of adults say they or someone in their household lost a job or wages during the pandemic, and half of those who did so are still earning less than before the pandemic).

[26] *See id.* (finding that, during the pandemic, Black and low-income workers are more likely to have incurred debt or put off paying household bills due to lost income); A. Barroso & R. Kochhar, *In the pandemic, the share of unpartnered moms at work fell more sharply than among other parents*, Pew Rsch. (Nov. 4, 2020), https://www.pewresearch.org/fact-tank/2020/11/24/in-the-pandemic-the-share-of-unpartnered-moms-at-work-fell-more-sharply-than-among-other-parents/ (finding steepest declines among Black and Hispanic single mothers and single mothers with young children).

percent of U.S. counties lack an abortion clinic, and, nationwide, 38% of women of reproductive age live in those counties.[27] A survey of a nationally representative sample of more than 8,000 abortion patients found that the average distance traveled to reach the clinic was 68 miles round-trip.[28] In a majority of states, at least one in five women of reproductive age lives more than 50 miles from the nearest clinic.[29] While rural women are most likely to face significant travel distances,[30] women in many cities must also travel significant distances to obtain abortion care: for instance, a 2018 study characterized 27 major U.S. cities as "abortion deserts" because they did not have a publicly advertised facility that provides abortions within 100 miles.[31]

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[27] Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States*, *2014*, 49 Persp. on Sexual & Reprod. Health 17, 20 (2017), https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12015. Today, 95% of abortions are performed in clinics (rather than doctors' offices or hospitals). *Id.* at 17.

[28] Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623, 1625 (2019), https://pubmed.ncbi.nlm.nih.gov/31282804/.

[29] Jonathan M. Bearak et al., *Disparities and Change Over Time in Distance Women Would Need to Travel to Have an Abortion in the USA: A Spatial Analysis*, Lancet Pub. Health e493, e495–96 (2017), https://www.thelancet.come/action/showPDF?pii=S2468-2667%2817%2930158-5 (in six states, a majority live more than 50 miles away, including two where a majority live more than 150 miles from the nearest provider).

[30] *See, e.g.*, Nicole E. Johns et al., *Distance Traveled for Medicaid-Covered Abortion Care in California*, 17 BMC Health Serv. Res. 287, 294 (2017), https://doi.org/10.1186/s12913-017-2241-0 (more than half of rural women in California traveled more than 50 miles to obtain an abortion); Bearak et al., *supra* note 29, at e497 (identifying swath of rural counties in the middle of the United States with travel distances of more than 180 miles to nearest abortion clinic).

[31] Alice Cartwright et al., *Identifying National Availability of Abortion Care and Distance from Major US Cities: Systematic Online Search*, 20 J. Med. Internet Res. 7 (2018), https://www.jmir.org/2018/5/e186/.

20. I understand that the Mifeprex REMS increases the distance that many women must travel to obtain a medication abortion, both by diminishing the number of medication abortion providers across the country (thus increasing the distance or number of trips patients must make to access care), and by preventing medication abortion providers from delivering mifepristone care to their eligible patients using telemedicine and mail (*i.e.*, but for the REMS, those patients would not have to travel at all to get the care they need).

21. As detailed below, the costs and burdens associated with increased travel and/or multiple trips to obtain an abortion typically include transportation, child care, and missed work, and may also include lodging, increased food costs (while traveling), and other unexpected expenses. There are also nonfinancial costs, as the logistics and time associated with travel, and the need to raise money for travel and associated costs, will often require the patient to share the fact of her abortion with people, such as household members and employers, whom she otherwise would not wish to tell—which may put her at risk for domestic violence or jeopardize her employment.

22. In my expert opinion, the overwhelming majority of people seeking abortions nationwide who have incomes too low to meet their basic needs—at *minimum*, three out of four abortion patients—suffer significant harm as a result of these added costs and burdens. Many are delayed in accessing this time-sensitive

care while they raise funds and make travel and logistical arrangements; some are blocked from obtaining an abortion at all because they cannot afford and navigate these costs and complications, or because they cannot safely share their abortion decision with household members or employers. Even those who are able to obtain an abortion despite these hurdles will have to make harmful trade-offs to do so—such as forgoing groceries or other medical care for themselves or their families, failing to pay bills including those for heat or rent, which puts the family at risk of losing their utilities or housing, or otherwise incurring debts that could have long-term consequences for household stability—or be forced to compromise their privacy and safety to access care.

Travel and Transportation

23. The additional travel costs necessitated by the REMS in order to access a medication abortion impose substantial burdens for low-income women. Even local trips of relatively short distances can present significant financial and logistical challenges for low-income women, who—as discussed above—are typically already struggling to afford basic household needs. And those costs and burdens are compounded for patients who live a considerable distance from the nearest medication abortion provider and who may have to incur significant financial costs for transportation, time off from work, child care, and potentially meals away from home, and lodging in order to access care.

24. For people with incomes below the minimum basic needs budget for their area, *any* added expenses—like refilling a gas tank, or taking a relatively short taxi ride—can stretch already strained and overextended budgets. The logistical burdens of arranging a trip to a REMS-certified provider can be especially challenging for those living in the majority of places in the United States with limited or essentially no public transportation options, particularly given that 9% of all households in the U.S. and 24% of households with incomes below the OPM do not have a vehicle, or have access to a vehicle.[32] Even if a low-income woman has access to a car, it may be shared among multiple people, which can limit access in practice, thus delaying care or forcing patients to disclose their abortion to others.

25. These burdens are compounded for those women who live farther from a REMS-certified provider and who may have to travel outside their county or state to access care. Cars owned by low-income households are older on average[33] and therefore less dependable for long journeys. And, for those without access to a

[32] *See* N. McGuckin & A. Fucci, U.S. Dept. of Transp., Summary of Travel Trends 2017 National Household Travel Survey 60, at Table 17, (2018) [hereinafter "NHTS 2017 Summary"], https://nhts.ornl.gov/assets/2017_nhts_summary_travel_trends.pdf; U.S. Dep't of Transp., Fed. Highway Admin., FHWA NHTS BRIEF 2014: Mobility Challenges for Households in Poverty 2. (2014), https://nhts.ornl.gov/briefs/PovertyBrief.pdf.

[33] NHTS 2017 Summary, *supra* note 32, at 8, 20; *see also* Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences For Patients Traveling for Services: Qualitative Findings from Two States*, 49 Perspectives on Sexual & Reprod. Health 95, 98 (2017) (in qualitative study of abortion patients in New Mexico and Michigan who crossed state lines or traveled long distances, factors including "limited access to safe and reliable transportation, or the need to use multiple means of transport[] significantly increased the time it took women to travel even relatively short distances" to access abortion care).

private car, bus or other transportation options between cities may be limited or inaccessible. For example, for a patient in Phillipston, MA,[34] there are abortion providers approximately 30 miles away in Worcester, MA,[35] and Keene, NH. But given limited public transportation options, traveling to Worcester would take at minimum 4 hours and three bus transfers, at an estimated round-trip cost of $42.50[36]; traveling to Keene, NH, would require five transfers and more than a day of travel.[37] For a patient in Cullowhee (Jackson County), NC, there are no public transportation options available to the nearest provider approximately 50 miles away in Asheville;

[34] With the exception of Kaua'i, Hawai'i, all other locations used to provide examples of travel distances, routes, and costs in this section are drawn from the same subset of counties in states with poverty rates similar to regional and national averages listed in Exhibit H-2.

[35] All distances to nearest providers are based on a search of publicly listed abortion clinics via Planned Parenthood, https://www.plannedparenthood.org/ (last visited Apr. 8, 2021), and *Find a Provider*, National Abortion Fed'n, https://prochoice.org/patients/find-a-provider/ (last visited Apr. 8, 2021). Driving distances in this section are estimated using Google Maps, assuming uncongested travel times. Bus, train, and flight fares assumed travel within two weeks of search.

[36] *See MART Trip Planner*, Montachusetts Reg'l Trans. Auth., http://www.mrta.us/trip-planner (search start: "Phillipston, MA," and finish: "Worcester, MA"). The Athol Link bus service departs Phillipston approximately every 90 minutes between 5:45 a.m. and 6:00 p.m., Monday through Friday. Patients would need to transfer at the Gardner City Hall stop to the Wachusett Shuttle line, which, at the time of search, was operating on a limited schedule of only four departures per day (6:05 a.m., 8:20 a.m., 1:05 p.m., and 6:05 p.m.). Patients would then need to transfer again at the MART Intermodal Transportation Center to the Clinton-Worcester Commuter Shuttle (commuter line, only running in morning hours) or the Worcester Shuttle (only three departures per day) for service to downtown Worcester. For full route schedules and fares, see *Routes and Schedules*, Montachusetts Reg'l Trans. Auth., http://www.mrta.us/routes-schedules (last visited Apr. 9, 2021), and *Fares and Passes*, Montachusetts Reg'l Trans. Auth, http://www.mrta.us/farespasses (last visited Apr. 9, 2021). Patients would also need to arrange transportation from home to the departure station and from the arrival station to the clinic.

[37] *See MART Trip Planner*, *supra* note 36. Although my search identified other clinics within 50 miles of Phillipston, travel by public transportation was similarly complicated for all options, involving multiple transfers and multiple-hour trips.

she would have to take a taxi all the way to the outskirts of the city to reach the closest bus stop, at a cost of $140–170.[38] For the families living below the Self-Sufficiency Standards for those states, these added expenses and lengthy travel time—not to mention the time and effort necessary to navigate multiple bus schedules and transfers in potentially unfamiliar locations—may be insurmountable.

26. Furthermore, routes and departure times are often very limited—even more so now, as some services reduced routes during the pandemic and have not yet resumed full service. If available arrival times do not align with available appointment times, even trips of only moderate distance may turn into more expensive cab rides,[39] or require overnight stays, requiring lodging and increasing child care costs and time away from work.

27. The burdens continue to increase for the sizeable percentage of women traveling especially long distances of 100 miles or more each way to access abortion care,[40] such as those in Quartzsite, AZ (La Paz County), who must travel

[38] *See* Rome2Rio, https://www.rome2rio.com/map/Asheville/Cullowhee (last visited Apr. 9, 2021).

[39] For example, a taxi between Phillipston and Worcester could cost approximately $110 one way, or $220 round-trip. *See* Taxi Fare Finder, https://www.taxifarefinder.com/ (last visited Apr. 12, 2021) (searching for "Phillipston, Massachusetts," to "Worcester, Massachusetts," and selecting "Cheapest" filter).

[40] *See, e.g.*, Bearak et al., *supra* note 29 (majority of women of reproductive age in North Dakota and Wyoming and one in five women in Alaska, Idaho, Kansas, Missouri, Montana, New Mexico, and South Dakota lived more than 100 miles from the nearest provider).

approximately 125 miles each way to reach a provider in Phoenix, AZ,[41] or Dalhart (Dallam County), TX, who must travel 200 miles each way to Lubbock, TX.[42] In extreme cases, such as for patients living in Hawai‘i or in other states with island populations (such as Alaska, Maine, North Carolina, and Florida), air travel may be required to access in-person abortion care. For example, in Hawai‘i, I understand that there are no clinics offering abortion care on the islands of Kaua‘i, Hawai‘i, Lana‘i, Moloka‘i, and Ni‘ihau, necessitating inter-island travel to O‘ahu to reach the nearest abortion provider. Since these arrangements are often made within a short timeframe, the costs tend to be higher than for long-planned travel. For example, the lowest round-trip ticket to O‘ahu (bought for travel within two weeks of purchase) was $178 for Kona, Lihu’e, or Hilo, according to Kayak.com.[43] On top of flight costs, abortion patients would also need to pay for ground transportation to and from the airport and/or overnight parking. For those living on Hawai‘i, the price of a taxi to or from the Hilo airport can run from $12 for people living in Hilo to $104 for

[41] Approximately 2 hours by car or bus ($56–62 round-trip, depending on how many days in advance of travel reservation is made, with only 4:00 a.m. departures and 10:30 p.m. returns available). *See Book A Trip*, Greyhound, https://www.greyhound.com/en (last visited Apr. 11, 2021). Clinics in El Centro, CA, and Coachella, CA, are similar distances by car, but options by bus take much longer and are more expensive.

[42] Approximately 3 hours by car. There is no bus service directly from Dalhart. Patients would have to arrange transportation to Dumas, TX (approximately 35 miles away), for bus service to Lubbock (at least 3.5–5 hours, depending on schedule), at a total round-trip cost of $200–280, including a taxi from Dalhart to Dumas. *See* Greyhound, *supra* note 41; Rome2Rio, https://www.rome2rio.com/map/Dalhart/Lubbock (last visited Apr. 11, 2021).

[43] Kayak.com, http://www.kayak.com (last visited April 7, 2021).

people living in Honoka'a.[44] Additionally, the cost of public transportation once on O'ahu is $5.50 per day. Thus, for a woman from Honoka'a traveling to Honolulu for abortion care, the cost of ground transportation alone (in both places) can exceed $219.[45] In addition, for many low-income women, particularly those for whom English is a second language and/or non-citizens, air travel may pose psychological and emotional hurdles, as it requires security checks, identification that may not be regularly needed, and simply the unfamiliarity of airplane travel.

28. Finally, for those who have to travel long distances or inter-island—such as patients in Hawai'i, Buffalo (Dallas County), MO (320 miles round-trip to Kansas City, KS), or Dalhart, TX (400 miles round trip to Lubbock)—travel for abortion may require overnight lodging,[46] for example, because of limited bus

[44] *Taxicab*, Hawaii.gov: Hilo Int'l Airport, http://airports.hawaii.gov/ito/getting-to-from/ground-transportation/taxicab (last visited April 7, 2021). For patients with cars, the cost of parking at the Hilo airport is $15 per day. *Parking*, Hawaii.gov: Hilo Int'l Airport, http://airports.hawaii.gov/ito/getting-to-from/parking/ (last visited April 7, 2021). Like many other places in the United States, Hawai'i has poor public transportation options, especially outside of O'ahu, and visitors to the counties of Hawai'i and Kaua'i, for example, are strongly urged to rent a car or use taxis for local transportation. *See* Sheila Beal, *What are the public transportation options in Hawaii*, Go Visit Hawaii (Oct. 23, 2017), https://www.govisithawaii.com/2017/10/10/what-are-the-public-transportation-options-in-hawaii/; *Transportation Rankings*, U.S. News, https://www.usnews.com/news/best-states/rankings/infrastructure/transportation (last visited April 7, 2021) (ranking the state of Hawaii 40th in terms of transportation infrastructure).

[45] *Adult Fare*, The Bus: City and County of Honolulu, http://www.thebus.org/Fare/Adultfare.asp (last visited April 7, 2021).

[46] *See, e.g.*, Caitlin Gerdts et al., *Impact of Clinic Closures on Women Obtaining Abortion Services After Implementation of a Restrictive Law in Texas*, 106 Am. J. Pub. Health 857, 861–63 (2016) (in study of Texas abortion patients whose nearest abortion clinic had closed as a result of a 2013 law, 16% reported having to stay overnight to access abortion care).

schedules, to accommodate early morning appointments, to obtain the least expensive bus or flight ticket, or if the round-trip distance is too far to travel in a single day.[47] Such costs are typically higher if reservations must be made just a few days or weeks ahead of time. According to a discount website, the cost of lodging starts around $83 in Honolulu, $43 in Lubbock TX, and $49 in Kansas City, KS.[48]

29. Especially for women already struggling to make ends meet, the added costs and logistical burdens of arranging transportation to a REMS-certified provider can be onerous, if not insurmountable.

Missed Work

30. Traveling to pick up a pill in person at a hospital, clinic, or medical office instead of receiving it by mail at home, or traveling to a second health care facility because the provider who diagnosed a patient's pregnancy cannot write them a prescription for Mifeprex, also may interfere with patients' work schedules. Women who have to travel long distances to reach a REMS-certified prescriber may

[47] For example, there is no direct bus service out of Buffalo, MO. To reach Kansas City, KS, a patient would first need to figure out how to get to Springfield, MO, 30 miles away. From there, she could take a Greyhound bus to Kansas City, MO, and then a shuttle to Kansas City, KS, at a cost of $62–104 round-trip (depending on how many days in advance she makes the reservation), not including the cost of getting to Springfield and back. In addition, there is only one bus per day between Springfield and Kansas City, departing at 2:15 p.m., and arriving at approximately 6:00 p.m. Accordingly, she would also likely need to travel the day before her appointment and stay overnight. *See* Greyhound, *supra* note 41 (no results for "Buffalo, MO"; results for travel to Kansas City, MO, from Springfield). Alternative options from Springfield include, *e.g.*, a 4.5-hour bus at a cost of $130 round-trip to St. Louis, MO, or a 3.5-hour bus ride each way at a cost of approximately $72–96 round trip to Tulsa, OK, which would also likely require an overnight stay. *Id.*

[48] *See* Hotels.com, https://www.hotels.com/ (last visited Apr. 11, 2021).

miss multiple days of work. Especially for low-income workers, the burdens associated with arranging time off work can result in delayed care, lost income, and even threats to job security.

31. About 40% of women workers in the United States have no paid time off.[49] Among low-wage workers (the bottom 25%), 93% lack paid family leave and 49% lack paid sick leave[50]; and almost two-thirds of workers in jobs that do not require a college degree lack paid personal days.[51] For part-time workers,[52] 92% lack paid family leave, three-quarters have no paid sick leave, and two-thirds lack any paid vacation or holidays.[53] For those without paid time off, any time away from work in order to access abortion care translates into lost wages. According to one study, the mean wages lost as a result of traveling for abortion care because of missed

[49] Cynthia Hess et al, Inst. for Women's Pol'y Res., The Status of Women in the States: 2015, at 88 (2015), https://iwpr.org/wp-content/uploads/2020/08/R400-FINAL-8.25.2015.pdf.

[50] Pronita Gupta et al., Paid Family and Medical Leave is Critical for Low-wage Workers and Their Families 1 (Dec. 2018), https://www.clasp.org/publications/fact-sheet/paid-family-and-medical-leave-critical-low-wage-workers-and-their-families.

[51] Gregory Acs & Pamela Loprest, Urb. Inst., Employers in the Low-Skill Labor Market, Brief No. 2: Low-Skill Jobs, Work Hours, and Paid Time Off 4 (2008), https://www.urban.org/sites/default/files/publication/32211/411802-Low-Skill-Jobs-Work-Hours-and-Paid-Time-Off.PDF.

[52] Twenty-five percent of women workers are employed in a part-time position. *Economics Daily: Percentage of Employed Women Working Full Time Little Changed Over Past 5 Decades*, U.S. Bureau of Lab. Statistics (Dec. 1, 2017), https://www.bls.gov/opub/ted/2017/percentage-of-employed-women-working-full-time-little-changed-over-past-5-decades.htm?view_full.

[53] Gupta, *supra* note 50, at 1; Hess et al, *supra* note 49, at 89.

work was $198 nationally.[54]

32. Missing one or more days from work not only means lost wages, but may also put the job itself at risk, leading to economic instability. In many cases, low-wage workers have unpredictable hours or are required as a condition of employment to regularly work overtime, both of which make it difficult to reliably plan appointments and related travel during non-work hours. It can be extremely difficult for low-wage workers to get a particular day off, particularly on short notice. And taking unapproved time off to keep an appointment or travel for abortion care can cost a patient her job.

33. Furthermore, some jobs that provide sick leave or paid leave may nonetheless require documentation of the reason for the leave. Women reluctant to disclose their abortions to their employers may therefore be unable to use paid or unpaid leave, even if their employer technically provides it; and those who do disclose their reason may have the request denied by a hostile employer or be vulnerable to retaliation as a result of their abortion.

Child Care

34. As noted, approximately 60% of women seeking an abortion have at least one child.[55] Consequently, traveling for an abortion, or making an unnecessary

[54] Rachel K. Jones et al., *At What Cost? Payment for Abortion Care by U.S. Women*, 23 Women's Health Issues e173, e174 (2013), https://www.ncbi.nlm.nih.gov/pubmed/23660430.

[55] *CDC Abortion Surveillance*, *supra* note 12, at Table 7.

or additional trip to a health care facility in order to obtain an abortion, may require child care arrangements, including when the abortion patient is the child's primary caregiver, or when the time needed for the appointment and travel to and from does not align with the child or children's regular childcare or school hours.

35. Child care costs can take up a significant proportion of a low-wage worker's income. In Hawai'i, costs range from $372 per month for part-time child care for a school-aged child to $589 per month for full-time infant care. Among the largest cities in the eight representative states analyzed above, full-time monthly child care for a preschooler ranges from $973 in Kansas City, MO (Jackson County), to $2,509 in Boston, MA. In rural counties across these states, a preschooler's full-time child care ranges in cost from $471 in Dallas County, MO, to $1,047 in Sandisfield, MA. Altogether, child care for just one preschooler ranges from 17% to 28% of the monthly needs budget across these eight states, averaging 21% of the budget.

36. But the daily rate for emergency short-term child care is often even greater than the daily rate for a month- or year-long slot. In addition, because many child care options, such as at a center or family home, are only available during regular daytime work hours, if a patient must be away overnight, the costs of child care are considerably higher. And if a woman cannot find or afford paid child care that aligns with her appointment and travel time, she may need to turn to a friend,

family member, or neighbor—which may require disclosing the reason she will be away, impinging on her privacy.

The Consequences of Attempting to Pay for Abortion-Related Travel

37. As detailed above, the total out-of-pocket costs involved in accessing abortion care can be substantial compared to income. For more than half of women attaining an abortion in a multi-state 2014 study, out-of-pocket costs (not including lost wages) averaged more than one-third of their personal monthly income.[56] In order to pay for these costs, low-income patients often end up making economic trade-offs that, as noted above, can carry serious consequences for their health, safety, and long-term economic stability.[57]

38. Indeed, a 2016 study concluded that two-thirds of women find it difficult or very difficult to pay for an abortion, and that doing so prevented or delayed nearly half of abortion patients from paying for at least one other basic need, including bills, food, rent, child care, and medical care.[58] Diverting funds from other basic needs in order to access an abortion can lead to additional costs and serious consequences. For instance, if a patient diverts any amount of rent funds and

[56] Roberts et al., *supra* note 6, at e211, e214.

[57] *Id.* at e216.

[58] Deborah Karasek & Sarah C.M. Roberts, *Abortion Patients' Experience and Perceptions of Waiting Periods: Survey Evidence before Arizona's Two-visit 24-hour Mandatory Waiting Period Law*, 26 Women's Health Issues 60, 63 (2016), https://www.whijournal.com/article/S1049-3867(15)00161-9/fulltext.

therefore cannot pay her full rent, she and her family risk eviction. Other consequences of having to divert funds include utility cut-offs, having to rely on food pantries or food banks, skipping meals, missing car payments, forgoing needed medical or dental care, or losing a scarce spot in a child care program.[59] Each of these in turn can lead to major long-term harms such as job loss, food insecurity, and medical harm.[60]

39. The most common source of money for an abortion is from the man involved in the pregnancy.[61] But borrowing from a partner can be problematic for some women, particularly where the relationship itself is unhealthy. The disclosure that results from the need for resources to cover travel and other costs (as well as

[59] Sandra S. Butler & Luisa S. Deprez, *The Parents as Scholars Program: A Maine Success Story*, 17 Me. Pol'y Rev. 40 (2008), http://digitalcommons.library.umaine.edu/mpr/vol17/iss1/7.

[60] Insurance does not change this calculus. Approximately two-thirds of the states restrict Medicaid coverage for abortion. Alina Salganicoff et al., *Coverage for Abortion Services and the ACA*, Kaiser Family Found. (Sept. 19, 2014), https://www.kff.org/womens-health-policy/issue-brief/coverage-for-abortion-services-and-the-aca/. Even in the states that do provide such coverage, many low-income women cannot access it because, for example, the income-eligibility threshold is too low, they are undocumented, or the time necessary to enroll will delay their abortion care beyond the time when they can access a medication abortion. *See* Kaiser Family Found., Health Care Coverage for Immigrants (2020), https://www.kff.org/racial-equity-and-health-policy/fact-sheet/health-coverage-of-immigrants/. A multi-state 2014 study found that nearly one-third of patients who appeared eligible for Medicaid coverage based on income and state of residency did not use Medicaid to pay for their abortions. Roberts et al., *supra* note 6, at e216. Many private or marketplace plans do not cover abortion either. Salganicoff et al., *supra*. Given this and other barriers, the same 2014 study found that only one in four patients with private insurance had their abortion covered by insurance. Roberts et al., *supra* note 6, at e216. And, the pandemic has increased the number of households that have lost health insurance coverage due to job loss and the associated loss of employer-provided health insurance. Furthermore, even for those who have coverage, Medicaid and private insurance do not cover other travel-related costs, such as meals, child care, and lost wages.

[61] Jones et al. (2013), *supra* note 54, at e177.

assistance with the travel itself) may increase the risk of domestic violence,[62] a widespread problem across the country.[63]

40. Other tactics to raise funds carry their own risks and consequences. Borrowing money from a payday lender or credit card company can help pay for an emergency expense, but repaying such loans may result in a cycle of refinancing, with additional fees and compounding interest leading to increasing debt.

41. Monetary costs alone do not fully capture how disruptive having to travel for abortion care can be. At each step, from arranging care for children, to informing supervisors or coworkers, to securing transportation and lodging, to obtaining resources (whether borrowed or diverted from other needs), the psychological harm increases and the circle of people aware of the reason for travel widens, breaching patient privacy, putting relationships or employment at risk, and increasing the risk of domestic violence.[64]

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[62] Sarah CM Roberts, *Risk of Violence from The Man Involved In Pregnancy After Receiving or Being Denied An Abortion*, BMC Med. 12:144 (2014), at 1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4182793/.

[63] *See id.*; Ctrs. for Disease Control & Prevention, The National Intimate Partner and Sexual Violence Survey: 2015 Data Brief – Updated Release 2, 8 (2018) https://www.cdc.gov/violenceprevention/pdf/2015data-brief508.pdf (reporting that 43% of U.S. women had experienced some form of sexual violence in their lifetime, one in four experienced contact sexual violence, physical violence, or stalking by an intimate partner, and one in five experienced rape or attempted rape).

[64] Jill Barr-Walker et al., *Experience of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, PLOS ONE 14(4), at 18 (2019), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0209991 ("Participants discussed how the need to secure time off of work, arrange childcare, or borrow money for travel

C. Research Confirms That Increased Travel to Obtain an Abortion Delays or Blocks Care

42. An extensive body of research supports the analysis above, documenting that the burdens and costs associated with traveling for abortion care delay or prevent patients from accessing care, decrease confidentiality, and increase the likelihood of anti-abortion stigma from employers, families, and/or friends.[65]

43. Research confirms that the greater the distance a patient must travel to access abortion, the less likely that the abortion will occur. For instance, a 2017 study evaluating the impact of a 2013 law that closed 24 of 41 abortion clinics in Texas—and thus increased the distance to the nearest clinic for many Texas women—found that the number of abortions declined 17% across the state between 2012 and 2014.[66] The magnitude of the decline in abortion rates increased more substantially as the distance from a patient's county of residence to the nearest abortion clinic increased: when the change in distance to an abortion clinic was 25–49 miles, abortions decreased 25.3%; when the change was 50–99 miles, abortions decreased by 35.7%; and when the change was 100 miles or more, abortions decreased by 50.3%.[67]

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or the procedure necessitated disclosing their decision to have an abortion to people at work and in their personal lives.").

[65] *Id.* at 2 (summarizing findings of multiple studies).

[66] Daniel Grossman et al., *Change in Distance to Nearest Facility and Abortion in Texas, 2012 to 2014*, 317 JAMA Network 437, 437–38 (2017), http://sites.utexas.edu/txpep/files/2017/10/Grossman-et-al-HB2-Change-in-Distance-Abortion-JAMA-2017.pdf.

[67] *Id.* at 438.

44. Other studies have documented this same inverse relationship between travel distance and abortion rates even for relatively short increases in distance. In Washington state, when a decline in the number of abortion providers led to a 12 mile increase in travel distance for rural women, the abortion rate among that population decreased by 27%.[68] In Georgia, for every 10 miles of distance from the major abortion providers in Atlanta, the number of abortions declined by 6.7 per 1,000 live births.[69] And in Ohio, when clinics in Toledo and Lima closed, necessitating greater travel distances to reach an abortion provider, abortions rates in those counties and surrounding areas dropped by 25% or more the following year.[70]

45. The research literature also shows a complex interrelationship between travel costs, distance, and delay that in turn impacts access to abortion. Travel

[68] Sharon A. Dobie et al., *Abortion Services in Rural Washington State, 1983–1984 to 1993–1994: Availability and Outcomes*, 31 Fam. Plan. Persp. 241, 241–44 (1999), https://www.guttmacher.org/sites/default/files/article_files/3124199.pdf; *see also* Robert W. Brown et al., *Provider Availability, Race, and Abortion Demand*, 67 Southern Eco. J. 656, 658 (2001) (in Texas, an increase of 10% in the travel distance from a woman's county to the nearest city with an abortion provider was associated with a 2.3% decline in the abortion rate for white women, 2.7% for African-American women, and 5.0% for Hispanic women).

[69] James D. Shelton et al., *Abortion Utilization: Does Travel Distance Matter?*, 8 Fam. Plan. Persp. 260, 260–62 (1976), https://jstor.org/stable/pdf/2134397.pdf?seq=1#page_scan_tab_contents (also finding a significantly greater increase in abortions in two counties distant from Atlanta after new abortion providers opened there, as compared to other counties in the state).

[70] Alison H. Norris et al., *Abortion Access in Ohio's Changing Legislative Context, 2010–2018*, 110 Am. J. Pub Health 1228, 1232 (2020) (abortion rate in rural counties disproportionately affected by clinic closures decreased more than 30% over study period).

burdens and costs can lead to delays in obtaining an abortion, which in turn can result in a patient being unable to access medication abortion or being turned away from the abortion clinic because by the time the patient is able to obtain the funds and make the necessary arrangements to get there, her pregnancy has advanced beyond the window for medication abortion care or the latest point in pregnancy at which the clinic provides services.[71] At the same time, delays can increase both the cost of the procedure (which typically increases as pregnancy advances and is greater for procedural abortion than medication abortion) and the cost of travel (for instance, if a patient must pay for lodging for a two-day procedure during the second trimester), thus causing further delay.[72] A nationwide 2014 study found that, for patients who were near a clinic's limit or were turned away because they exceeded that limit, the most cited reason for the delay was costs, for both travel and the procedure.[73] A 2010

[71] *See* Jerman et al., *supra* note 33, at 95, 98 (in qualitative study of 29 women traveling across state lines or long distances to access abortion in New Mexico and Michigan, most common consequence of travel and related barriers was "obtain[ing] abortions at later gestations than desired because of delays"); *see also* Norris et al., *supra* note 70, at 1233 (finding that patients in Ohio have abortions later in pregnancy than the national average and that this disparity increased as the number of facilities offering care in the state diminished).

[72] Jerman et al., *supra* note 33, at 100 (describing the "negative feedback loop," in which delay caused by difficulty raising money can lead to higher procedure costs and further delay); Diane Greene Foster & Katrina Kimport, *Who Seeks Abortions at or After 20 Weeks?*, 45 Persp. on Sexual & Reprod. Health 210, 214–15 (2013), https://doi.org/10.1363/4521013 (women who were 20 weeks or more pregnant reported difficulty getting to an abortion facility, spent more on travel, and experienced more delay); Norris et al., *supra* note 70, at 1233 (period of legislative and regulatory changes in Ohio that reduced access and resulted in clinic closures coincided with Ohioans being increasingly more likely to access abortion at later gestational ages).

[73] Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, Am. J. Pub. Health 1687, 1689 (2014), https://doi.org/10.2105/AJPH.2013.301378 (finding that 58.3% of patients turned away and 67%

study in Illinois found that "[m]any women reported substantial difficulty locating a clinic, traveling long distances and finding transportation," and that such obstacles were associated with seeking abortion care in the second rather than the first trimester.[74]

III. CONCLUSION

46. At *least* three out of four abortion patients have income that is insufficient to meet their basic needs. The costs and burdens of traveling to obtain an abortion, arranging child care, and lost wages entirely prevent some women from obtaining abortion care. Even for those able to access care, these burdens force many patients to forgo other necessary expenses for themselves and their families and put them at risk of longer-term economic insecurity. In addition, these burdens force women to disclose their abortions to a wider circle of people than would otherwise be necessary, thus exposing some women and their families to domestic violence and/or longer-term economic insecurity.

arriving just before the limit attributed their delay to "travel and procedure costs," while 29.8% cited "not knowing how to get to a provider"; for first trimester patients, travel and procedure cost was the second-most cited reason, after "not recognizing pregnancy").

[74] Jessica W. Kiley et al., *Delays in Request for Pregnancy Termination: Comparison of Patients in the First and Second Trimesters*, 81 Contraception J. 446, 449 (2010), https://doi.org/10.1016/j.contraception.2009.12.021.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed in Friday Harbor, WA on April 12, 2021.

Diana M. Pearce

Diana M. Pearce, Ph.D.

Pearce Decl.

Appendix

APPENDIX: Comparison of Basic Needs Budgets in Eight States With Poverty Rates Close to National and Regional Averages

State Selection Methodology: To select states for this analysis, I used states that had poverty rates closest to the national and regional averages, according to U.S. Census Bureau data, and for which current Self-Sufficiency Standard data was available. State poverty rates and the national poverty rate refers to the latest two-year average (2018–19) provided by the Census Bureau.[1] To calculate regional averages, states were grouped by Census region: Northeast, Midwest, South, and West. The average regional percentage was then calculated using the state poverty rates for all states within that region. Finally, each state's percentage below-poverty was compared to the national average and the regional average, respectively, to determine the state or states closest to each average. If 2021 Self-Sufficiency Standard data was not available for the state with the closest rate to the national or regional average, the second-closest was used instead.

State Needs Budgets: For each state, I compared the Standard (*i.e.*, needs budget) for a family with one adult and one preschooler to the local or state minimum wage for (a) the county with the largest city; (b) the county with the median Standard in the state; and (c) the county with the lowest Standard in the state. The Standard was then compared to the minimum wage for each locality, assuming full-time work. Wherever possible, the cost of a given need in the Standard is based on the amount of financial assistance that the government (federal or state) has deemed minimally adequate for that basic need (such as housing, child care, or food expenses):

- Housing: maximum rent allowed for Section 8 voucher (housing assistance) recipients as set by the U.S. Department of Housing and Urban Development
- Child care: maximum amount set by the state for reimbursement for those receiving child care assistance (minus copayments)
- Food: the U.S. Department of Agriculture's "Low-Cost" Food Plan, which covers *only* the cost of basic groceries, without any take-out or restaurant food
- Transportation: cost of a monthly pass for local public transportation, or (if no adequate option) average cost of a private car, assuming use to/from work and one weekly shopping trip, based on national data such as U.S. Highway Administration's National Household Travel Survey, and U.S. Bureau of Labor Statistics' Consumer Expenditure Survey
- Health care: assuming employer-sponsored insurance and out-of-pocket costs based on the Medical Panel Survey, the most complete national source for health and insurance costs
- Miscellaneous: 10% of all other costs, and accounting only for essentials such as clothing, nonprescription medicines, and personal hygiene items, and not including any recreation, entertainment, savings, or debt repayment
- Taxes: federal and state income tax, payroll taxes, and state and local taxes (if applicable), and accounting for federal and applicable state tax credits

[1] *Income and Poverty in the United States*, U.S. Census Bureau, at Table: Percentage of People in Poverty by State Using 2- and 3-Year Averages: 2016–17 and 2018–19, https://www.census.gov/data/tables/2020/demo/income-poverty/p60-270.html (last visited Apr. 9, 2021).

National Average Poverty Rate (2018–19): 11.1%

Northeast
Average Poverty Rate (2018–19): 9.0%

	Closest to National Average			Closest to Regional Average		
	New York[2]			**Massachusetts[3]**		
	Largest city (Queens County)[4]	Median (Schoharie County)	Least expensive (Cattaraugus County)	Largest city (Boston)	Median (Phillipston)	Least expensive (Sandisfield)
Housing	$2,091	$938	$734	$2,509	$976	$1,175
Child care	$1,285	$840	$840	$1,502	$1,047	$1,047
Food	$471	$415	$371	$559	$470	$476
Transp'n	$127	$328	$315	$90	$308	$320
Health care	$535	$485	$451	$542	$534	$534
Misc.	$451	$301	$271	$520	$333	$355
Taxes	$1,469	$588	$434	$1,615	$789	$869
Earned Income Tax Credit	$0	$0	-$75	$0	$0	$0
Child Care Tax Credit	-$50	-$50	-$58	-$50	-$50	-$50
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$6,212	$3,678	$3,116	$7,120	$4,240	$4,559
Minimum Wage	$15.00	$12.50	$12.50	$13.50	$13.50	$13.50
Ratio (Self-Suff. to Min. Wage)	**2.4**	**1.7**	**1.4**	**3.0**	**1.8**	**1.9**

[2] The Northeastern state closest to the national average was Maine (11.0%), but current Standard data for Maine is not available. The second-closest to the national average was New York (11.8%).

[3] The Northeastern state closest to the national average was Rhode Island (9.0%), but current Standard data for Rhode Island is not available. The second-closest to the regional average was Massachusetts (8.1%). Standard data in Massachusetts is grouped by town, not county, because towns are the more meaningful local geographic unit under Massachusetts's government structure.

[4] The largest city in New York (New York City) spans multiple counties; of those, Kings County is the most populous, but its Standard data is divided into two sub-regions to capture cost variations within the county. Queens County, the second-largest, has county-wide Standard data and is used instead for ease of comparison.

Midwest
Average Poverty Rate (2018–19): 9.7%

	Closest to National Average			losest to Regional Average		
	Missouri[5]			**Illinois[6]**		
	Largest city (Jackson County)	Median (Adair County)	Least expensive (Dallas County)	Largest city (Cook County)	Median (Jersey County)	Least expensive (Pike County)
Housing	$973	$662	$662	$1,197	$791	$700
Child care	$782	$486	$471	$1,179	$647	$547
Food	$388	$347	$378	$384	$380	$358
Transp'n	$352	$331	$337	$100	$275	$266
Health care	$603	$720	$646	$446	$594	$565
Misc.	$310	$255	$249	$331	$269	$244
Taxes	$739	$443	$418	$857	$600	$473
Earned Income Tax Credit	$0	-$95	-$110	$0	-$41	-$137
Child Care Tax Credit	-$50	-$60	-$63	-$50	-$55	-$63
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$3,929	$2,922	$2,823	$4,277	$3,293	$2,787
Minimum Wage	$10.30	$10.30	$10.30	$13.00	$11.00	$11.00
Ratio (Self-Suff. to Min. Wage)	**2.2**	**1.6**	**1.6**	**1.9**	**1.7**	**1.5**

[5] Missouri's 2018–19 average poverty rate was 10.8%, the closest to the national average among Midwestern states.

[6] Illinois's 2018–19 average poverty rate was 9.8%, the closest to the regional average for Midwestern states.

South
Average Poverty Rate (2018–19): 13.2%

	Closest to National Average **Texas**[7]			Closest to Regional Average **North Carolina**[8]		
	Largest city (Harris County)	Median (Dallam County)	Least expensive (Uvalde County)	Largest city (Mecklenburg County)	Median (Jackson County)	Least expensive (Person County)
Housing	$1,129	$762	$734	$1,237	$718	$757
Child care	$788	$665	$509	$1,053	$688	$521
Food	$376	$374	$296	$435	$397	$375
Transp'n	$355	$311	$318	$301	$270	$276
Health care	$637	$683	$682	$495	$607	$454
Misc.	$329	$279	$254	$352	$268	$238
Taxes	$606	$458	$367	$880	$543	$405
Earned Income Tax Credit	$0	-$39	-$111	$0	-$47	-$136
Child Care Tax Credit	-$50	-$55	-$63	-$50	-$58	-$65
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$161
Monthly Self-Sufficiency Standard	$4,004	$3,272	$2,820	$4,536	$3,219	$2,664
Minimum Wage	$7.25	$7.25	$7.25	$7.25	$7.25	$7.25
Ratio (Self-Suff. to Min. Wage)	**3.2**	**2.6**	**2.2**	**3.6**	**2.6**	**2.1**

[7] The Southern state closest to the national average was Oklahoma (12.1%), but current Standard data for Oklahoma is not available. The second-closest to the national average was Texas (12.4%).

[8] North Carolina's 2018–19 average poverty rate was 12.9%, the closest to the regional average for Southern states.

West
Average Poverty Rate (2018–19): 10.2%

	Closest to National Average **California**[9]			Closest to Regional Average **Arizona**[10]		
	Largest city (Los Angeles County)	Median (Riverside County)	Least expensive (Modoc County)	Largest city (Maricopa County)	Median (La Paz County)	Least expensive (Santa Cruz County)
Housing	$2,058	$1,417	$807	$1,259	$952	$788
Child care	$1,447	$1,054	$757	$879	$630	$700
Food	$448	$408	$435	$408	$396	$334
Transp'n	$342	$340	$323	$269	$241	$241
Health care	$507	$511	$849	$518	$624	$484
Misc.	$480	$373	$317	$333	$284	$255
Taxes	$1,145	$727	$571	$688	$524	$399
Earned Income Tax Credit	$0	$0	$0	$0	-$15	-$103
Child Care Tax Credit	-$50	-$50	-$50	-$50	-$53	-$63
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$6,210	$4,613	$3,842	$4,138	$3,417	$2,868
Minimum Wage	$15.00	$14.00	$14.00	$12.15	$12.15	$12.15
Ratio (Self-Suff. to Min. Wage)	**2.4**	**1.9**	**1.6**	**2.0**	**1.6**	**1.4**

[9] California's 2018–19 average poverty rate was 11.0%, the closest to the national average among Western states.

[10] The Western state closest to the regional average was also California (11.0%). The second-closest was Arizona (11.4%).